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(54) Title: PRIMING DEVICE FOR MEDICAL INFUSION SYSTEMS

(57) Abstract: A priming device for a medical infusion system is provided, for enabling a fluid delivery tubing operatively connected to a liquid source to be automatically primed with liquid from the source during operation of the device. The device has a fluid inlet in fluid communication with a bypass outlet via a chamber. The fluid inlet is adapted for operative connection with the delivery tubing, and the bypass outlet has suitable air venting means for air venting at least gas away from the chamber during operation of said device. A suitable valve is provided, the valve being adapted for enabling liquid communication between the chamber and a valve outlet to be selectively prevented or allowed during operation of said device, according to predetermined conditions. Suitable connectors at the valve outlet enable connection of the device to a patient interface end such as a cannula. Medical infusion systems, such as intravenous infusion administration sets, or dialysis or bypass blood systems, incorporating such a device are also provided.

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PRIMING DEVICE FOR MEDICAL INFUSION SYSTEMS

Technical Field

The present invention relates to liquid administration systems which provide infusion of liquids to the vascular system of the body, including intravenous infusion administration sets, dialysis blood systems, bypass blood systems, and the like. In particular, the present invention relates to priming devices for such medical infusion systems such as to enable substantially complete self-priming or automatic priming of the infusion systems.

Background

Intravenous fluid administration is a well-known system used for infusing a host of fluids to patients, including blood, blood products, crystalloid and colloid solutions, drugs, and so on, as well as for infusing patient's own blood in a closed-loop procedure such as in dialysis, for example.

The typical method of use requires a cannula - typically teflon or another suitable plastic - to be introduced into a vein by a physician via a percutaneous puncture. Next, a bag with the required solution to be infused is prepared, usually by trained medical personnel, and the bag is connected to a tubing system. The tubing system generally comprises at least one clamp and a drip chamber, which is first filled with the solution followed by the rest of the tubing. When the attendant medical personnel has determined that the

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system is air free, the tubing system is connected to the cannula so that administration of the solution into the vein can proceed, as controlled via a roller clamp in a gravity feed set, or via the pump rate in a pump set.

The process of filing the tube system with solution up to the patient receiving end is known as priming, the main aim of which is to prevent air embolism, which, while rare, can be fatal when it occurs.

The actual priming process is not without problems. Even in ideal situations such as in routine non-emergency hospital infusions, priming requires some skill. To prevent spillage of the solution onto the patient or surroundings, it is common procedure to use a dish to collect initial fluid as it leaves the distal end of the tubing during the last stages of priming. While promoting patient comfort, avoidance of spillage is of particular importance when dealing with donor or patient blood, or poisonous or chemotrapic medications, which may be hazardous especially in cases of contact with the skin. This process tends to be lengthy and may expose the patient or medical staff to fluid spill. Medical staff therefore need to wear special gloves, and possibly aprons and so on, in such cases for protection against blood or hazardous solutions (such as cytotoxic agents), which raises the medical costs associated with the priming procedure.

When the bag of solution empties, air flows into the tubing system, necessitating the medical staff to be on alert to prevent blood being drawn into the tubing and/or air being introduced to the patient. Apart from the obvious psychological distress to the patient and family members, blood backflow may result in the coagulation and clotting of blood, which may then be re-introduced into the patient, which may seriously endanger the patient. Patient blood backflow also represents a risk to medical personnel in terms of

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blood born infections. The occurrence of blood backflow usually requires the infusion tubing to be replaced. On the other hand, the introduction of air into the patient is a hazard and may be potentially fatal to the patient. If more, or a different, solution needs to administered, the air in the tubing system has to be removed, and thus another priming process needs to be carried out. In order to save time, replacing the infusion administration set, additional priming and potential danger to the patient as well as blood cross-infection, medical staff tend to change the infusion bag well before it is emptied, thereby wasting about 15%-25% of each bag in the process. This leads to significant economic losses associated with the treatment.

In less favourable conditions, such as for patients who receive in the home total parenteral nutrition because of bowel dysfunction, or intravenous fluid infusion, for example, replacing the infusion administration set and performing proper priming of the tubing set may be problematic if not hazardous when carried out by non-professional people such as a family member.

In highly unfavorable conditions, such as in military conditions and/or emergency situations, when operating in poor lighting conditions and possibly in wet weather, it may be impossible even for highly trained and experienced medical staff to verify that the tubing system has been successfully primed, leading to severe stress in the part of the medical staff not to mention the potentially severe and even fatal consequences for the patient.

While a number of systems have been proposed to solve these problems, most attempt to address the same by ineffective and/or complex means.

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For example, US 5,308,333 provides an air filter and crack valve in series between the proximal and distal ends of an infusion pump tubing. The large and substantially flat air filter, which is typically very expensive compared to the total cost of the IV set, has a fluid inlet into a chamber, and a pair of air outlets via hydrophobic membranes. A fluid outlet in communication with the crack valve is provided via a hydrophylic membrane in the chamber. The crack valve is a one-way valve which is openable only when the pressure differential across the valve is greater than a predetermined value (the crack pressure of the valve). While the filter does provide a vent for air to be expelled from the fluid conduit, the presence of a hydrophylic filter considerably reduces the available flow rate for the fluid. More importantly, though, the system disclosed in this patent comprises a length of tubing between the filter unit and the crack valve, and between the crack valve and the patient connector, and thus air trapped in these sections cannot be expelled via the filter (because of the hydrophylic membrane) nor via the valve itself. Thus the system disclosed in this patent does not provide for total priming of the tubing, which has to be completed manually.

US 5,226,886 discloses a similar arrangement to US 5,308,333, but without the air filter unit, and therefore also necessitates the tubing to be manually primed by a user.

US 5,419,770 and US 5,290,238 each relate to a self-priming tubing set for an infusion device. Essentially, an intravenous (hereinafter, IV) delivery tubing is provided with an air and particle filter unit upstream of the patient interface end. The filter unit comprises a hydrophobic filter for removing air as fluid passes through the filter, and a hydrophilic filter downstream thereof. The air filter unit itself is composed of several parts bonded to the delivery tubing, and is thus to some extent complex structurally. Furthermore, the

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tubing downstream of the filter unit is of relatively small bore to reduce the dead space volume downstream of the filter and to provide a lower pressure at the venous access site, and thus different types of tubing are required upstream and downstream of the filter unit. The downstream end of the tubing must also be kept as short as possible for the reasons stated. A major disadvantage of this system is that it is imperative that the internal pressure of the infusion device containing the volume of fluid to be infused is kept below the bubble point of the air particle filter. Otherwise air will pass through the filter and into the patient, a potentially grave situation. Furthermore, the lack of a valve downstream of the filter unit may cause a number of problems. Under certain flow conditions air may be admitted through the hydrophobic filter into the upstream end of the of the delivery tubing. While this air cannot pass through the hydrophilic filter, its presence in the system is nonetheless undesirable. Further, under certain circumstances blood may be siphoned off the patient.

US 5,211,201 relates to an air elimination system for an IV fluid delivery system. An air detection apparatus is provided, and when this detects air bubbles in the delivery fluid a controller diverts fluid via a return line to the fluid bag by operating one or more valves. Fluid pressure is provided by a pump. There is no suggestion of complete automatic priming, and while the return line and valve system may be used effectively to prime the intravenous fluid line, it requires control of the valves via the controller and possibly with the air of the air detection apparatus. Thus the system disclosed in this patent is substantially complex and not practical for use in situations such home infusions, or battlefield/emergency conditions.

In US 4,248,223 a length of tubing between the liquid source and the patient interface end is carried out by providing a source of pressurised liquid

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downstream of the interface having a predetermined amount of liquid. A clamp normally closes off this pressurised liquid source until the apparatus is needed, when on opening the clamp, liquid is introduced into the tubing therefrom, automatically purging air therefrom. Thus, the source of pressurised liquid adds complexity and cost to the system.

US 5,853,397 relates to a safety valve for which is disposed in a tubing between a pump and the patient interface. The safety valve is set to open at pressure greater than the pressure head provided by the source of liquid, but lower than the pressure provided by the pump, and thus prevents liquid to be accidentally infused to the patient when the pump is turned off. There is no disclosure or suggestion as to self-priming of tubing.

US 4,246,932 and US 4,729,401 relate to various valve assemblies used in medical liquid circuits. However these valves are neither directed to, nor permit, the self-priming of infusion systems connected to the vascular system via tubing.

Many other patents are directed to self-priming filters for use with IV sets, but while many such filters themselves may be self-priming, there is no teaching as to how the length of tubing between the filter and the patient interface may be primed automatically. The air trapped in this length of tubing is generally of a significant volume and needs to be purged (in the prior art, manually) prior to initiating fluid flow to a patient.

Similar problems to those described above are sometimes encountered during the priming of dialysis and bypass blood circuits. In dialysis blood circuits blood is diverted from the body to a dialysis system, and then rerouted back

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to the vascular system of the patient, using appropriate tubing. In bypass blood circuits, blood is diverted from the heart, through a dipulmonary bypass circuit, for example, and rerouted back to the patient via tubing connected to the heart. In both types of blood circuits, as indeed in other medical systems in which liquid from whatever source is introduced into the vascular system of the body via tubing, many of the components such as filters etc. may be self priming. However, in such systems there exists at least a length of tubing from the liquid source (or from the last self-primed component in the circuit) to the vascular system needs to be primed with liquid prior to opening fluid communication between the source and the vascular system.

It is therefore an aim of the present invention to provide a device and method which overcomes the limitations of infusion administration set devices, dialysis and bypass blood circuit systems, and other medical systems in which liquid is channelled into the vascular system of a patient from outside of the body via tubing, and associated methods of operation thereof.

It is another aim of the present invention to provide a priming device for enabling automatic and substantially complete self-priming of tubing, in particular infusion administration sets, dialysis blood circuits and bypass blood circuits.

It is another aim of the present invention to provide such a device that is simple to use.

It is another aim of the present invention to provide such a device that is relatively simple mechanically and thus economic to produce.

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It is another aim of the present invention to provide such a device that is readily connectable to an infusion administration set, or a dialysis or bypass blood circuit system, such as to permit the same to be primed in a safe and reliable manner.

It is another aim of the present invention to provide such a device having a downstream valve for controlling fluid delivery to the patient, and a venting means for diverting air in the tubing that is to be primed in a direction away from the patient.

It is another aim of the present invention to provide any one of an infusion administration set, or a dialysis blood circuit system, or a bypass blood circuit system, comprising such a priming device integrally or releasably connected thereto.

The present invention achieves these and other aims by providing a self-priming system particularly for medical infusion systems, including infusion administration sets, dialysis and bypass blood circuits. A length of primary tubing comprises a distal end, adapted for connection to a patient interface such as a needle or cannula, and a proximal end, adapted for connection to a source of liquid to be infused to the patient. The proximal end may comprise a shut-off valve such as a pinch clamp or roller clamp, and a drip chamber. A valve means comprised in the priming device according to the invention, is selectively openable under predetermined conditions to permit the liquid to flow from the source of liquid to the interface, and thus to the patient. The distal end also comprises a venting means upstream of the valve means to enable air trapped within the tubing to be expelled therethrough while the tubing is being primed with the liquid. The venting means is characterised in having an inlet portion close to the upstream end of

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the valve means and an outlet portion adapted for dealing with the air expelled from the primary tubing. The outlet portion may thus comprise a suitable one-way hydrophobic filter or suitable one-way valve, or may comprise a length of bypass tubing routed to a drip chamber comprised between the proximal end of the primary tubing and the liquid source. Alternatively, the outlet portion may comprise a length of tubing having a vacuum (formed therein prior to operating the device - typically at manufacture) and an upstream second valve, the second valve being opened to enable the air in the primary tubing to be collected there. Such a vacuum may also help to speed up the priming procedure, particularly when small bore infusion tubing is used. The valve at the distal end of the primary tubing may be adapted to open at a preset pressure differential and may thus comprise, for example, a suitable diaphragm valve, duckbill valve, ball valve or other type of valve means. Such a valve means may be adapted to open when the liquid from the liquid source reaches the valve, all air having been expelled via the vent and bypass tubing, and a predetermined pressure head is set up by holding the liquid source at a predetermined height from the valve, for example. Alternatively, the valve means may be adapted to be opened manually at the convenience of the user. The self-priming system may be used as follows. The clamp is unclamped enabling liquid to flow distally through the primary tubing, at the same time expelling the dead volume of air initially contained in this tubing via the vent. When the liquid has reached the valve, and preferably when the liquid has continued up the bypass tubing to fully expel the air, the system is primed and ready to initiate the flow of liquid to the patient via the distal end. The valve means may then be opened, either manually or by virtue of the appropriate pressure differential. Since the bypass tubing of the device has its inlet portion close to the upstream inlet end of the valve, it is ensured that no air gets trapped thereat.

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Optionally, a vacuum source may be provided at the venting outlet to accelerate the priming process. Advantageously, the primary tubing and the bypass tubing may be in the form of a single tubing having a double lumen.

The automatic liquid priming that may be achieved with the present invention simplifies and reduces risks to patients in hospital and home care environments, and in particular in emergency/bad weather/military conditions, in which it is not possible, or very difficult, or hazardous for medical personnel to evaluate the efficacy of manual priming using known systems. The present invention also provides a non-spill self-priming system which is particularly useful for applications involving chemotherapy and/or radioactive materials, and for avoiding the risk of blood born infections.

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Summary of Invention

In a first aspect of the present invention, a priming device is provided for enabling at least a portion of a first tubing operatively connected to a liquid source to be selectively completely primed with liquid from said source during operation of the device, comprising:-

a housing defining a chamber and comprising a fluid inlet in fluid communication with a bypass outlet via said chamber, said fluid inlet adapted for operative connection with said first tubing via a first end thereof for providing fluid communication between said tubing and said chamber during operation of said device;

suitable air venting means in fluid communication with said bypass outlet for enabling at least gas to be vented from said chamber during operation of said device; and

valve means having a valve inlet and a valve outlet, said valve inlet adapted for providing liquid communication when open with said chamber, said valve means adapted for enabling liquid communication between said chamber and said valve outlet to be selectively prevented or allowed during operation of said device, according to predetermined conditions.

The predetermined conditions preferably comprise allowing or preventing fluid communication between said chamber and said valve outlet, according to whether or not said chamber is substantially filled with said liquid. Preferably, the valve is adapted for allowing communication between the chamber and the valve outlet when the differential fluid pressure therebetween exceeds a predetermined value, and this fluid pressure may be provided by liquid pressure of a liquid comprised in said chamber during

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operation of said device. Advantageously, the predetermined fluid pressure differential is provided by a predetermined head of liquid comprised in said tubing during operation of said device. The valve means may comprise for example a suitable duckbill valve, diaphragm valve or ball valve. Alternatively, the valve means may be externally actuable for allowing communication between the chamber and the valve outlet when required by a user.

The device may further comprise a connection means in fluid communication with said valve outlet, said connection means being adapted for operative connection to a suitable patient interface. Alternatively, the device may comprise such an interface integrally or otherwise connected to the valve outlet and in communication therewith. The patient interface typically comprises a suitable cannula, needle or the like that is adapted for introduction into the body of a patient.

In a first embodiment of the invention, the air venting means comprises a suitable anti-reingestion means for enabling air to pass therethrough form said chamber to an outside thereof, but substantially prevents entry of air therethrough from said outside the device into the chamber, said suitable means typically being connected in near to or at said bypass outlet. Such air venting means may comprise a suitable one-way valve arrangement, or a suitable hydrophobic filter arrangement.

In a second embodiment of the present invention, the air venting means comprises a second tubing of a predetermined length and having a first end thereof connected to said bypass outlet and having a second end thereof connected to a suitable hydrophobic filter or one-way valve arrangement to provide fluid communication between said filter and said bypass outlet, such

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as to enable gas to be diverted to an outside of said device from said chamber, while preventing said liquid from being similarly diverted. The air venting means may comprise a second tubing of a predetermined length and having a first end thereof connected to said bypass outlet and having a second end thereof closed, and further comprising a clamp means to clamp at least said second tubing such as to close fluid communication between a first portion of said second tubing downstream of said clamp to a second portion of said tubing upstream of said clamp, wherein said first portion of said second tubing is in a substantially evacuated state prior to operation of said device, wherein operation of said device is by releasing said clamp and opening fluid communication between said second portion of said first tubing and said chamber via said first portion.

In a third embodiment of the present invention, the liquid source comprises suitable drip chamber and a clamp means, wherein said first tubing is operatively connected to said liquid source via said drip chamber, said clamp means adapted to clamp at least said first tubing such as to selectively close or open fluid communication between a first portion of said first tubing comprised between said clamp and said drip chamber, to a second portion of said tubing downstream of said clamp, wherein said air venting means comprises a second tubing of a predetermined length and having a first end thereof connected to said bypass outlet and having a second end thereof connectable to said drip chamber at a location above the operational liquid level of the drip chamber such as to enable gas to be diverted to said drip chamber via said second tubing while substantially preventing liquid from said drip chamber to flow through said second tubing, wherein operation of said device is by releasing said clamp means and opening fluid

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communication between said first portion and said second portion of said first tubing.

In a fourth embodiment of the present invention, the air venting means comprises a second tubing having a first end thereof connected to said bypass outlet and having a second end thereof operatively connected to a suitable vacuum source, and further comprising a clamp means to clamp at least said second tubing such as to close fluid communication between a first portion of said second tubing upstream of said clamp and including the vacuum source to a second portion of said second tubing downstream of said clamp, wherein operation of said device is by releasing said clamp and opening fluid communication between said first tubing and said vacuum source.

The self-priming device according to the present invention may further comprise a suitable filter having a liquid inlet and a liquid outlet, said liquid outlet being in open communication with said fluid inlet of said device, and wherein said fluid inlet is adapted for connection to said first tubing via said liquid inlet of said filter. The filter is preferably an air eliminating filter, and may be integrally connected to said fluid inlet, or removably connected to said fluid inlet by means of suitable connectors comprised in said liquid outlet and aid fluid inlet. In some embodiments, the filter comprises a length of tubing providing communication between said liquid outlet and said fluid inlet such as to enable the said filter to be displaced vertically above the said device by a predetermined height, which is typically less than the head of liquid required to open said valve means.

In the second through fifth embodiments, the priming device optionally further comprises a suitable one-way means or anti-reingestion means for enabling air to pass therethrough form said chamber to said second tubing,

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and for substantially preventing entry of air therethrough from said second tubing into the chamber, said suitable means. Such one-way means may comprise a suitable one-way valve arrangement or a suitable hydrophobic filter arrangement, for example. In these embodiments, the second tubing is optionally further adapted for substantially parallel and juxtaposed alignment with respect to said first tubing when said device is connected to said first tubing, for example by comprising suitable clamping means whereby to enable at least an upstream portion of said second tubing to be connected to an at least a downstream portion of said first tubing.

The priming device of the first through fifth embodiments is preferably adapted for use with a medical infusion system, said medical infusion system comprising said a first tubing operatively connected to said liquid source, and wherein said fluid inlet comprises a suitable connector for connecting with a compatible connector comprised at a downstream end of said infusion administration set. Such a medical infusion system may comprise any one of an infusion administration set, a dialysis blood system or a bypass blood system.

According to a second aspect of the present invention, a substantially completely self priming infusion administration set is provided comprising:-

first tubing means having a first end and a second end, said second end being adapted for operative connection to a suitable liquid source;

a priming device as previously described, in which the fluid inlet being connected to said first end of said first tubing, wherein said device is adapted to connection to a patient via suitable patient interface means.

The set typically further comprises one or more of the following:-

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a source of liquid operatively connected to said second end of said first tubing;

a suitable drip chamber and a clamp means, wherein said first tubing is operatively connected to said liquid source via said drip chamber, said clamp means adapted to clamp at least said first tubing such as to selectively close or open fluid communication between a first portion of said first tubing comprised between said clamp and said drip chamber, to a second portion of said tubing downstream of said clamp;

a suitable roller clamp operatively connected to said first tubing and adapted for regulating the flow from said liquid source via said first tubing;

a suitable pump operatively connected to said first tubing and adapted for regulating the flow from said liquid source via said first tubing.

In a sixth embodiment of the invention, the air venting means comprises a suitable means for enabling air to pass therethrough form said chamber to an outside thereof, and for substantially preventing entry of air therethrough from said outside the device into the chamber, said suitable means being connected in near to or at said bypass outlet. Such air venting means comprises a suitable one-way valve arrangement or a suitable hydrophobic filter arrangement, for example.

In a seventh embodiment of the invention, the air venting means comprises a second tubing of a predetermined length and having a first end thereof connected to said bypass outlet and having a second end thereof connected to a suitable hydrophobic filter or one-way valve to provide fluid communication between said filter and said bypass outlet, such as to enable

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gas to be diverted to an outside of said device from said chamber, while preventing said liquid from being similarly diverted.

In a eighth embodiment of the invention, the air venting means comprises a second tubing having a first end thereof connected to said bypass outlet and having a closed second end, and further comprising a clamp means to clamp at least said first tubing such as to close fluid communication between a first portion of said first tubing upstream of said clamp to a second portion of said tubing downstream of said clamp, wherein said second portion of said first tubing, said chamber and said second tubing comprise are in an evacuated state prior to operation of said device, wherein operation of said device is by releasing said clamp and opening fluid communication between said first portion and said second portion of said first tubing. Optionally, the clamp simultaneously clamps said first tubing and said second tubing at least prior to operation of said device.

In a ninth embodiment of the invention, the air venting means comprises a second tubing having a first end thereof connected to said bypass outlet and having a second end thereof connected to a drip chamber at a location above the operational liquid level thereof such as to enable gas to be diverted to said drip chamber via said second tubing while substantially preventing liquid from said drip chamber to flow through said second tubing, said first tubing being operatively connected to said liquid source via said drip chamber and further comprising a clamp means to clamp at least said first tubing such as to selectively close or open fluid communication between a first portion of said first tubing comprised between said clamp and said drip chamber, to a second portion of said tubing downstream of said clamp, wherein operation of said device is by releasing said clamp and opening fluid communication between said first portion and said second portion of said first tubing.

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In an tenth embodiment of the invention, the air venting means comprises a second tubing having a first end thereof connected to said bypass outlet and having a second end thereof operatively connected to a suitable vacuum source, and further comprising a clamp means to clamp at least said second tubing such as to close fluid communication between a first portion of said second tubing upstream of said clamp and including the vacuum source to a second portion of said second tubing downstream of said clamp, wherein said second portion of said first tubing, said chamber and said second tubing comprise are in fluid communication, wherein operation of said device is by releasing said clamp and opening fluid communication between said first tubing and said vacuum source. Optionally, the clamp simultaneously clamps said first tubing and said second tubing at least prior to operation of said device.

In an eleventh embodiment, the liquid source comprises suitable drip chamber and a clamp means, wherein said first tubing is operatively connected to said liquid source via said drip chamber, said clamp means adapted to clamp at least said first tubing such as to selectively close or open fluid communication between a first portion of said first tubing comprised between said clamp and said drip chamber, to a second portion of said tubing downstream of said clamp, wherein said air venting means comprises a second tubing of a predetermined length and having a first end thereof connected to said bypass outlet and having a second end thereof connectable to said drip chamber at a location above the operational liquid level of the drip chamber such as to enable gas to be diverted to said drip chamber via said second tubing while substantially preventing liquid from said drip chamber to flow through said second tubing, wherein operation of said device

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is by releasing said clamp means and opening fluid communication between said first portion and said second portion of said first tubing.

In the sixth through eleventh embodiments, the first tubing may be integrally connected to said fluid inlet. Alternatively, the first tubing may be connected to said fluid inlet via suitable connectors comprised at said fluid inlet and said first end of said first tubing.

The seventh through eleventh embodiments preferably further comprise suitable one-way means or anti-reingestion means for enabling air to pass therethrough form said chamber to said second tubing, and for substantially preventing entry of air therethrough from said second tubing into the chamber, said suitable means. The one-way means may comprise a suitable second one-way valve arrangement or a suitable hydrophobic filter arrangement, for example. Further optionally, at least an upstream portion of said second tubing is integrally connected to an at least a downstream portion of said first tubing. Preferably, the upstream portion of said second tubing and said downstream portion of said first tubing are formed as a double lumen tubing.

According to the second aspect of the present invention, a substantially completely self priming medical infusion system is also provided comprising:-

first tubing means having a first end and a second end, said second end being adapted for operative connection to a suitable liquid source;

a priming device as described for the sixth through eleventh embodiments, *mutatis mutandis*, said fluid inlet being connected to said first end of said first tubing, wherein said priming device is adapted to

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connection to a patient's vascular system via suitable patient interface means.

Such a self priming medical infusion system may comprise a dialysis blood system or a bypass blood system, for example.

Description of Figures

Figure 1 illustrates schematically the main elements in a typical infusion administration set of the prior art.

Figure 2 illustrates schematically the main elements in a typical infusion administration set comprising the priming device according to a first aspect of the present invention.

Figure 3(a) illustrates schematically, in cross-sectional view, a first embodiment of the present invention. Figure 3(b) and Figure 3(c) illustrate the embodiment of Figure 3(a) comprising a filter connected thereto.

Figures 4(a) to 4(d) illustrate schematically, alternative configurations of the embodiment of Figure 3(a).

Figure 5 illustrates schematically, a second embodiment of the present invention connected to a regular IV infusion administration set of Figure 1.

Figure 6 illustrates schematically, a third embodiment of the present invention.

Figure 7 illustrates schematically, a fourth embodiment of the present.

Figure 8 illustrates schematically, a fifth embodiment of the present invention.

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Figure 9 illustrates schematically the main elements of an infusion administration set according to a second aspect and a sixth embodiment of the present invention.

Figure 10 illustrates schematically, in cross-sectional view, a priming device comprised in the embodiment of Figure 9.

Figures 11(a) to 11(d) illustrate schematically alternative configurations of the device of Figure 10: Figure 11(a) in cross-sectional view; Figure 11(b) along X-X in Figure 11(a); Figure 11(c) alternative cross-sectional view to Figure 11(b); Figure 11(d) alternative cross-sectional view to Figure 11(b).

Figure 12 illustrates schematically, a seventh embodiment of the present invention.

Figure 13 illustrates schematically, an eighth embodiment of the present invention.

Figure 14 illustrates schematically, a ninth embodiment of the present invention.

Figure 15 illustrates schematically, a tenth embodiment of the present invention.

Figure 16 illustrates schematically, an eleventh embodiment of the present invention.

Figure 17(a) to 17(c) illustrate schematically a flow control device according to another aspect of the present invention: Figure 17(a) in transverse cross-sectional view; Figure 17(b) along Q-Q of Figure 17(a); Figure 17(c) along P-P of Figure 17(a).

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Disclosure of Invention

The present invention is defined by the claims, the contents of which are to be read as included within the disclosure of the specification, and will now be described by way of example with reference to the accompanying Figures.

In the present specification, the term downstream refers to a direction along the direction of flow of a fluid, generally from a source of liquid and toward a patient, while the term upstream refers to a direction generally opposed to the direction of flow of a fluid.

In the present specification the term fluid is taken to include gases as well as liquids.

Referring to Figure 1, a typical intravenous infusion administration set (100) of the art comprises a liquid source (170), such as a sack of a solution or medication, having a delivery tubing (140) connected thereto via a drip chamber (190). The delivery tubing (140) has a suitable patient interface connector (180) at the downstream end thereof for connecting the tubing (140) to the patient, typically via a cannula (210) embedded in the body of the patient (200). The infusion administration set (100) may further comprise a roller clamp (150) or pump (160) for regulating the flow rate of liquid to the patient in a gravity feed set or a pump set, respectively, and/or a clamp (155) (such as a pinch clamp or slide clamp, for example) for selectively allowing or preventing flow of liquid through the tubing (140). Before delivery of liquid from the sack (170) to the patient can begin, at least the portion of the delivery tubing (140) upstream of the connector (180) must be purged of air,

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otherwise the air remaining in the tubing is drawn into the vascular system of the patient, leading to a potentially fatal embolism.

The present invention relates primarily to a priming device for enabling self-priming or automatic priming of medical infusion systems. Medical infusion systems are herein defined as liquid administration systems which provide infusion of liquids to the vascular system of the body, and thus include intravenous infusion administration sets, dialysis blood systems, bypass blood systems, and the like. Such liquids may be external supplied, or may originate from the patient, such as blood for example. The priming device according to the present invention enables a length of tubing extending upstream of a patient interface end to be selectively primed by a user in a simple and spill-free manner with liquid directly or indirectly originating from a liquid source, such as a bag of solution and/or patient blood and/or donor blood, at the upstream end of the medical infusion system. The priming device is connectable to the tubing and enables air trapped in the tubing before the infusion process to be diverted from the patient interface end until at least the tubing is filled with liquid, whereupon a valve comprised in the priming device and normally closed now permits the liquid to flow towards the patient interface end, which is comprised in or is connectable to the priming device. The present invention also relates to self-priming or automatic-priming medical infusion systems, including infusion administration sets, dialysis and bypass blood systems, incorporating such a priming device upstream of the patient interface end.

In a first embodiment of the present invention, according to a first aspect of the invention, and referring to Figure 2 and Figure 3(a), a priming device,

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designated by the numeral (10), is provided for connection with any suitable infusion administration set that comprises a length of tubing connected or connectable at one upstream thereof to a liquid source, and at the other downstream end thereof to a patient via a suitable connector, for example. For the purposes of illustration, the device (10) will be described in relation to a regular infusion administration set such as the infusion administration set (100) hereinbefore described, which comprises, inter alia, a liquid source (170) such as a sack of solution or medication, for example, and a liquid delivery downstream end having a suitable connector (180). Of course, the device (10) may be used in conjunction with any other liquid administration systems which provide infusion of liquids to the vascular system of the body, including dialysis blood systems, bypass blood systems, and the like, for example connected to a suitable liquid source that may comprise a portion of an infusion system using patient's own blood in closed-loop procedure, in a manner similar to that described herein with respect to the regular infusion administration set (100), *mutatis mutandis*.

The device (10) generally comprises a housing (20), a valve means (50), and a diverting means (60). The housing (20) defines a chamber (30) and comprises a fluid inlet (22) in fluid communication with a bypass outlet (24) via said chamber (30). The fluid inlet (22) is operatively connectable to a first tubing means, which in this embodiment is the delivery tubing (140) of the infusion administration set (100), via a downstream end (142) of the tubing (140), providing fluid communication between said delivery tubing (140) and said chamber (30) during operation of said device (10).

Thus, the fluid inlet (22) may comprise any suitable tubing connection means (23), such as a luer lock for example. Preferably the connection means (23) is compatible with the connector (180) provided at the downstream end of

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delivery tubing (140) of the infusion administration set (100). The connector (180) at the liquid delivery or downstream end of tubing (140) of a regular infusion administration set (100) typically consists of a patient interface end connector, such as a luer lock for example, enabling the connection of the infusion administration set (100) to a patient. In the first aspect of the present invention, the connector (180) of a regular infusion administration set (100) is connected via connection means (23) to the priming device (10), which in turn comprises a suitable connector (85) which acts as the patient interface connector, enabling the infusion administration set to be connected to the patient.

The said bypass outlet (24) is operatively connectable to suitable air venting means (60), providing at least gaseous communication between said chamber (30) and said air venting means (60). Said air venting means (60) is adapted for air venting at least gas away from said chamber (30), and possibly also some liquid, during operation of said device (10), as will be further described hereinbelow.

The priming device (10) may take any one of a plurality of forms. For example, as illustrated in Figure 3(a), the housing (20) may have the fluid inlet (22) and bypass outlet (24) in the form of ports integrally formed therewith, the chamber (30) being in the form of a plenum, and the valve means (50) comprised within the housing (20). Alternatively, as illustrated in Figure 4(a) to 4(d), the valve means (50) may be comprised outside the housing, and the fluid inlet (22) and the bypass outlet (24) being in the form of a T-junction type arrangement of varying shapes, including U- V- and Y-shaped junctions, wherein the piece of tubing joining the fluid inlet (22) and the bypass outlet (24) constitutes the chamber (30).

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The valve means (50) may be adapted to be accommodated within the housing (20) as illustrated, or alternatively to be mounted outside the housing.

The patient interface end (80) is adapted for operative connection to a patient, and may comprise any one of a number of known interface systems. For example, the patient interface end (80) comprises a suitable connector (85) adapted for connection to a complementary inlet comprised in a suitable cannula that is adapted for introduction into the body of a patient.

The valve means (50) comprises a valve outlet (54) in liquid communication with the patient interface end (80), which comprises connector (85). The valve means (50) also comprises a valve inlet (52) which is normally closed and which provides liquid communication between the chamber (30) and the valve means (50) when open. The valve means (50) is adapted for enabling liquid communication between said chamber (30) and said valve outlet (54) (and therefore between the infusion administration set (100) via said tubing (140) and the patient interface end (80)) to be selectively prevented or allowed, typically according to whether said chamber (30) comprises gas or liquid, respectively, during operation of said device (10).

In preferred embodiments of the present invention, the valve means (50) is adapted for automatically allowing communication between the chamber (30) and the valve outlet (54) (and therefore the patient interface end (80)) when the differential fluid pressure across the valve means (50) exceeds a predetermined value. There are many examples of suitable valves means (50) in the art capable of remaining closed until a predetermined pressure

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difference across the valve opens the valve. Examples of such valves include so-called crack valves, diaphragm valves, duckbill valves, ball valves and so on. Advantageously, the valve means (50) may be designed to have an opening pressure differential that matches a gauge liquid pressure in said chamber (30) provided by a convenient head (h) of liquid in said tubing (140). A typical target value for (h) may be 60 cm to about 70 cm. Thus, with the liquid source (170) held above the device (10) as the liquid descends through tubing (140), air downstream of the liquid front is expelled from the chamber (30) via the bypass outlet (24) and air venting means (60). When liquid reaches and fills the chamber (30), the head of liquid within the tubing (140) and up to the chamber (30) being (h) then causes the valve means (50) to open and thus allow liquid to flow to the patient via interface (80). Thus, by simply placing the liquid source (170) and tubing (140) (and adjusting drip chamber (190) and clamp (150) or (155) as required) at a predetermined vertical spacing from the chamber (30), the full length of tubing (140) as well as chamber (30), will be automatically primed with liquid, and only then will the valve means (50) open to allow liquid to flow to the patient. Thus, the required fluid pressure may be provided during operation of said device. A great advantage with pressure-differential type of valves (50) is that they require the pressure differential to be maintained in order to remain open. Thus, if for any reason air gets introduced into the downstream portion of the tubing (140), the pressure head automatically drops, closing off the valve, particularly by the time the air reaches the chamber (30). Furthermore, the valve means (50) also automatically closes when the liquid source (170) is emptied, since the pressure head in the tubing (140) drops to below that required to keep the valve means (50) open, thereby enabling practically the full contents of each liquid source (170), which often comprises expensive

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solutions, to be used safely, without fear of air from the source (170) being drawn into the patient.

Alternatively (or indeed additionally), the valve (50) may be externally actuable for allowing communication between the chamber and the valve outlet (54) when required by a user. Thus, a user may manually open the valve means (50) when he has determined that all of the air in the tubing (140) has been expelled from the chamber (30), and a column of air-free liquid now exists between the chamber (30) and an upstream end of tube (140). In such a case, the housing (20) is preferably transparent or translucent, or at least comprises a transparent window that enables a user to view the contents of chamber (30).

In all embodiments the valve means (50) advantageously also acts as a one-way valve, thereby preventing back flow of blood from the patient into the rest of the infusion administration set, which can then be used repeatedly. Furthermore, this feature also prevents psychological distress to the patient and visitors such as relatives, which may otherwise arise when realising that blood is "draining" out of the patient and into the tubing.

According to the first aspect of the present invention, the device (10) comprises air venting means (60) which are operatively connected to said bypass outlet (24), providing at least gaseous communication, and in some embodiments also partial liquid communication, between said chamber (30) and said air venting means (60). Said air venting means (60) is adapted for venting air, and optionally also liquid, from said chamber (30) during operation of said device (10), as will be further described hereinbelow.

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In a first embodiment of the present invention, and referring to Figure 3(a), said air venting means comprises suitable anti-reingestion means (63) for enabling air to pass therethrough form said chamber (30) to the outside atmosphere, but substantially prevents entry, or reingestion of the same or other air therethrough from outside the device (10) into the chamber (30). Thus, the said anti-reingestion means (63) may comprise any suitable one-way valve arrangement, typically similar to the said valve means (50) herein described, *mutatis mutandis*. However, such anti-reingestion means (63) situated at the outlet (24), while providing a compact device (10), may require a long period for priming the infusion administration set (100), and/or, may result in spillage of liquid therethrough to outside the device (10), albeit less than would normally be spilled when manually priming the set (100) without the device (10).

In a second embodiment of the present invention, and referring to Figure 5, said air venting means (60) comprises a second tubing (300) having a first end (320) thereof connected to said bypass outlet (24). The second tubing (300) further comprises a second end (330) connected to any suitable device that enables air to pass therethrough while preventing the flow of liquid therethrough - such as for example a suitable outlet one-way valve, such as for example a float valve, or indeed to a suitable outlet hydrophobic filter (340) - to provide fluid communication between said hydrophobic filter (340) and said bypass outlet (24). Thus, air may be diverted to an external environment and thus away from said chamber (30) via the one-way valve or hydrophobic filter (340), while preventing said liquid from being similarly passing therethrough. Advantageously, the said second tubing comprises clamping means (66), such as for example one or more plastic clips, for

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clamping the tubing (300) to the delivery tubing (140) of the infusion administration set (100) in a juxtaposed manner along at least part of the length of the tubing (300). During normal operation of the device (10) according to the second embodiment, the tubing (300) is clamped to the delivery tubing (140) after connection of the device (10) to the infusion administration set (100) via connectors (23), (180). The clamping means (66) generally ensures that the tubing (300) and the end (330) are kept in a compact configuration with delivery tubing (140). This minimises potential accidents in which the tube (300) could be accidentally detached from the device (10) or otherwise damaged, and moreover ensures that generally the second end (330) is maintained at the same level as the first end (320).

However, should the second end (320) drop to a height below that of the first end (310), air that may still be in tube (300) could be displaced back upstream in the direction of the device (10), and in fact re-enter the chamber (30). This in itself would not normally pose a threat to the patient, as the valve means (50) would typically automatically close when there is only air in chamber (30). For example, if valve means (50) comprises a crack valve that opens at a particular crack pressure equivalent to a certain head of liquid in delivery tubing (140), as soon as the chamber (30) refills with air, the pressure difference across the valve automatically diminishes, closing the valve means (50) and preventing air from entering the patient. Nevertheless, there is a disadvantage in that at least the chamber (30), if not part of the tubing (140) as well, needs to be re-primed, which thus interrupts the flow of liquid to the patient from source (170), which may have negative consequences for the patient. Thus, in embodiments of the present invention in which the air venting means (60) comprises a length of tubing extending from the outlet (24), such as in the second embodiment for example, the

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device (10) advantageously optionally further comprises suitable means (64), for enabling air to pass therethrough form said chamber (30) to the tubing, but substantially prevents entry of air therefrom back into the chamber (30). Thus, anti-reingestion means (64) may be similar to the anti-reingestion means (63) or valve means (50) described with respect to the first embodiment, *mutatis mutandis*.

In a third embodiment of the present invention, and referring to Figure 6, the air venting means (60) comprises a second tubing (400) having a first end (420) thereof connected to said bypass outlet (24) and having a second end thereof (430) closed. A clamp (480') clamps at least said second tubing (400) at an upstream end (420) thereof near the outlet (24) such as to close fluid communication between the chamber (30) and the tubing (400). The second tubing (400) is initially in an evacuated state prior to operation of said device (10). Operation of the device (10) is by releasing said clamp (480') and thereby opening fluid communication between said delivery tubing (140) and second tubing (400), whereupon liquid flows into chamber (30) and at least part of second tubing (400) on account of the vacuum previously present therein. Optionally, air may be drawn into the drip chamber (190) via a hydrophobic filter (95). Further optionally, the device (10) may comprise said anti-reingestion means (64) for enabling air to pass therethrough form said chamber (30) to the tubing (400), and for substantially preventing entry of air therefrom back into the chamber (30). Preferably, the clamping means (66) are provided for clamping the tubing (400) to said delivery tubing (140) in juxtaposed arrangement, in a manner similar to that described for the first embodiment, *mutatis mutandis*.

In a fourth embodiment of the present invention, and referring to Figure 7, the air venting means (60), comprises the same structural elements as the

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third embodiment, with the exception of the said closed end (430) of second tubing (400), as hereinbefore described, *mutatis mutandis*. Instead of having a closed second end (430), in the fourth embodiment, the second end (430") is connected to a vacuum source (450) which provides a suitable vacuum to the second tubing (400). The vacuum source (450) may comprise, for example, a syringe that is manually or automatically actuable, or alternatively a spring loaded bellows arrangement set to expand manually or automatically, or a pump, or indeed any suitable means capable of creating a suction force with respect to the second tubing (400). The clamp means (480') closes the vacuum source (450) from the chamber (30) and from delivery tubing (140). Optionally, though, the clamp means (480') may also close a lower portion of the second tubing (400) from its upper portion, and thus the clamp means (480') may lie closer to the vacuum source (450) than the outlet (24). Operation of the device (10) is by releasing said clamp (480') and thereby opening fluid communication between said delivery tubing (140), the second tubing (400) and the vacuum means (450), whereupon liquid flows into the chamber (30) and at least part of second tubing (400) on account of the vacuum previously present and/or the vacuum provided by the vacuum source (450). The vacuum provided by the vacuum source (450) serves to accelerate the priming procedure, particularly when the infusion tubing comprises narrow lumens. Optionally, the device (10) may comprise said anti-reingestion means (64) for enabling air to pass therethrough form said chamber (30) to the tubing (400), and for substantially preventing entry of air therefrom back into the chamber (30). Preferably, the clamping means (66) are provided for clamping the tubing (400) to said delivery tubing (140) in juxtaposed arrangement, in a manner similar to that described for the first embodiment, *mutatis mutandis*.

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In a fifth embodiment of the present invention, and referring to Figure 8, the air venting means (60) comprises a second tubing (500) having a first end (520) thereof connected to said bypass outlet (24) and having a second end (530) thereof connected to the drip chamber (190) at a location above the operational liquid level (92) thereof. Thus air may be diverted to said drip chamber (190) via said second tubing (500) while substantially preventing liquid from said drip chamber (190) to flow through said second tubing (500). In this embodiment, a clamp means (155) clamps at least said delivery tubing (140) such as to selectively close or open fluid communication between a first portion (143) of said first tubing (140) comprised between said clamp (155) and said drip chamber 1(90), and a second portion (144) of said tubing (140) downstream of said clamp (155). Operation of this embodiment is by releasing said clamp (155) and thus opening fluid communication between said first portion (144) and said second portion (143) of said first tubing (140). Liquid descends down the second portion (143), into chamber (30), and up second tubing (500) until the levels of liquid in both tubings (140), (500) are equalised, and the air comprised in these tubings is pushed out from the upper end (530) of the second tubing (500) and into the drip chamber (190). The valve means (50) is set to open under these conditions. Optionally, air may be drawn into the drip chamber (190) via a hydrophobic filter (95).

Optionally, a pump (160) may be provided between the clamp (155) and the drip chamber (90). Further optionally, the device (10) may comprise said anti-reingestion means (64) for enabling air to pass therethrough form said chamber (30) to the tubing (400), and for substantially preventing entry of air therefrom back into the chamber (30). Preferably, the clamping means (66)

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are provided for clamping the tubing (500) to said delivery tubing (140) in juxtaposed arrangement, in a manner similar to that described for the first embodiment, *mutatis mutandis*.

In all embodiments, the device (10) may be connectable to a delivery tubing (140) via any suitable filter, and/or indeed to any component of an external infusion administration set, either directly or indirectly, as required. The filter (140) is preferably of the air-eliminating type, i.e., that expels air therefrom during operation thereof, commonly referred to as self-priming filters. In particular, and referring to Figure 3(b), such a filter (82) may be integrally connected to said fluid inlet (22), typically via a length of tubing (83), and the upstream end of the filter (82) comprises a suitable connector (86) which has the same function as connector (23) of Figure 3(a), *mutatis mutandis*, enabling the device (10) including the filter (82) to be connected to delivery tubing (140). Alternatively, and referring to Figure 3(c), the filter (82) may be connected, releasably or permanently, to the fluid inlet (22) via a suitable connector (84) that is compatible with connector (23) of the device (10). As before, the filter (82) comprises a suitable connector (86) which has the same function as connector (23) of Figure 3(a), *mutatis mutandis*, enabling the device (10) including the filter (82) to be connected to delivery tubing (140). While the filter (82) has the nominal function of filtering the liquids to be infused to the patient, it may also act in an advantageous manner with respect to the priming device (10). For example, as the liquid source (170) is depleted, in the normal course of events liquid would continue to be administered to the patient until the valve (50) is closed, typically automatically as the head in the delivery tubing (140) drops to a predetermined threshold. As the liquid source (170) is changed, this procedure requires priming to be performed in at least a part of the delivery

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tubing from the new source (170) up to the patient interface. Such a procedure may be lengthy or inconvenient, as a downstream part of the tubing (140) as well as the device (10) is already primed, and the new air that it is desired to purge has to pass through these components prior to being expelled via the venting means (60). The filter (82), being self-priming, enables the length of tubing from the liquid source (170) to the filter (82) to be primed in the normal manner, thereby doing away with having to re-prime the whole system via the device (10), which may now be used immediately. However, if the filter (82) is provided at a vertical distance from the device (10) less than that required to maintain the valve (50) open (wherein said valve (50) operates according to a pressure differential across it given by a certain height of liquid upstream of the valve (50)), then when the liquid source is removed, the valve will close before liquid has drained from the filter (82) itself. In such a case, replacing the liquid source (170) only requires the length of tubing between the source (170) and the filter (82) to be primed, and this may be achieved via the air-eliminating filter (82).

According to a second aspect of the present invention, and referring to Figure 9 and Figure 10, a substantially completely self-priming or automatically-priming infusion administration set (900) is provided comprising a length of tubing (40) connected to or connectable to a suitable liquid source (70) at an upstream end thereof and to a priming device (10') at a downstream end thereof. Thus, referring to Figure 9, the first tubing (40) may be operatively connected to the liquid source (70) via a drip chamber (90). Furthermore, a roller clamp (150) or pump (160) may be provided typically downstream of the drip chamber (90) for regulating the flow of liquid through the first tubing (40), in the case of gravity feed or pump sets,

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respectively. Furthermore, and additional clamp (155) may be provided for selectively opening and closing the flow of liquid through the tubing (40). Thus, and for the purposes of illustration, the nominally completely self-priming infusion administration set (900) is described as comprising a priming device (10'). Of course, other liquid administration systems which provide infusion of liquids to the vascular system of the body, including dialysis blood systems, bypass blood systems, and the like, for example may comprise the priming device (10') is connected to a suitable liquid source that may comprise a portion of an infusion system using patient's own blood in closed-loop procedure, for example, in a manner similar to that described herein with respect to the self-priming IV infusion administration set (900), *mutatis mutandis*.

The priming device (10') according to the second aspect of the present invention may be releasably connected to said tubing via suitable connectors, and may thus be similar to the priming device (10) described herein with respect to the first aspect of the present invention, *mutatis mutandis*.

Alternatively, the priming device (10') according to the second aspect of the present invention may be integrally connected to said tubing (40) via the downstream end thereof. Thus, referring to Figure 10, the priming device (10') may be similar to the priming device (10) described herein with respect to the first aspect of the present invention, *mutatis mutandis*, with the optional exception that rather than comprise said connector (23), the inlet (22) may be integrally connected to the tubing (40). Alternatively, and as illustrated in Figures 11(a) to 11(d), the housing (20') of the priming device (10') may be configured with an open top, the opening being in the form of a

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figure-of-eight, complementary to the outer profile of a double-lumen tube (250). The double lumen tube (250) sealingly fits into the housing (20), and one each of the free juxtaposed ends of the lumens acts as one of the fluid inlet (22) and the bypass outlet (24).

In a sixth embodiment of the present invention, and referring to Figure 10, said air venting means (60) of the priming device (10') of said self-priming infusion administration set (900) comprises suitable anti-reingestion means (63) for enabling air to pass therethrough form said chamber (30) to the outside atmosphere, but substantially prevents entry of air therethrough from outside the device (10) into the chamber (30), as described herein with respect to the first embodiment, *mutatis mutandis*.

In a seventh embodiment of the present invention, and referring to Figure 12, said air venting means (60) of the priming device (10') of said self-priming infusion administration set (900) comprises the components of the air venting means as described for the second embodiment of the present invention, *mutatis mutandis*. Optionally, and advantageously, the said second tubing (300) in the seventh embodiment is in substantially parallel and juxtaposed alignment with respect to said first tubing (40), and the second tubing may be clamped to the first tubing (40) by means of clamps similar to the clamps (66) described with respect to the second embodiment, *mutatis mutandis*. Alternatively, and as illustrated in Figure 12, at least an upstream portion of said second tubing (300) is integrally connected to a corresponding downstream portion of said first tubing (40). Optionally, the lower, upstream portion of said second tubing (300) and a corresponding lower, downstream

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portion of said first tubing (40) may be integrally formed as a double lumen tubing. Then, the lower part of the double lumen tubing may be bifurcated to integrally or otherwise connect with the priming device (10') at inlet (22) and outlet (24). Alternatively, the lower part of the double lumen tubing may connect to the housing (20') in a manner similar to that described in connection with Figure 11(a) to Figure 11(d). Optionally, air may be drawn into the drip chamber (90) via a hydrophobic filter (95). Further optionally, the device (10') may comprise said anti-reingestion means (64) for enabling air to pass therethrough form said chamber (30) to the tubing (300), and for substantially preventing entry of air therefrom back into the chamber (30), in a manner similar to that described for the first embodiment, *mutatis mutandis*.

In an eighth embodiment of the present invention, and referring to Figure 13, the air venting means (60) is similar in some respects to that of the third embodiment as hereinbefore described, *mutatis mutandis*, with some differences, as will become evident. The air venting means (60) of the eighth embodiment comprises a second tubing (400) having a first end (420) thereof connected to said bypass outlet (24) and having a second end thereof (430) closed. A clamp (480) clamps at least said first tubing (40) such as to close fluid communication between a first portion (43) of said first tubing (40) upstream of said clamp (480) and a second portion (44) of said tubing (40) downstream of said clamp (480). The second portion (44) of said first tubing (40), said chamber (30) and at least a lower portion (444) of said second tubing (400) are initially in an evacuated state prior to operation of said device (10). Operation of the infusion administration set (900) is by releasing said clamp (480) and thereby opening fluid communication between said first portion (43) and said second portion (44) of said first tubing (40), whereupon

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liquid flows into the second portion (44), chamber (30) and at least part of second tubing (400) on account of the vacuum previously present. Optionally, air may be drawn into the drip chamber (90) via a hydrophobic filter (95). Optionally, the device (10') may comprise said anti-reingestion means (64) for enabling air to pass therethrough form said chamber (30) to the tubing (400), and for substantially preventing entry of air therefrom back into the chamber (30), in a manner similar to that described for the first embodiment, *mutatis mutandis*.

In a ninth embodiment of the present invention, and referring to Figure 14, the air venting means (60) comprises the same structural elements as the eighth embodiment of Figure 13, with the exception of the said closed end (430) of second tubing (400), as hereinbefore described, *mutatis mutandis*. Instead of having a closed second end (430), in the ninth embodiment, the second end (430') of the second tubing (400) is routed to a location in the drip chamber (90) above the regular liquid level (92). A suitable one-way valve (164) is provided in the upper portion (443), preferably at the downstream end thereof within the bubble chamber (90), to prevent ingestion thereinto of air from the bubble chamber (90). The clamp means (480) closes the lower ends (44) and (444) of the first tubing (40) and second tubing (400), respectively, from their corresponding upper portions, (43), (443), respectively. The lower portions (44), (444) are initially in an evacuated state prior to operation of said device (10). Operation of the infusion administration set (900) is by releasing said clamp (480) and thereby opening fluid communication between said first portion (43) and said second portion (44) of said first tubing (40), and between the lower and upper portions of the second tubing (400) whereupon liquid flows into the second portion (44), chamber (30) and at least part of second tubing (400) on account of the

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vacuum previously present. The vacuum is formed before operating the apparatus, typically during the manufacture thereof, and serves to accelerate the priming procedure, particularly when the infusion tubing comprises narrow lumens. Optionally, the end (430') may comprise a suitable one-way valve such as a ball valve. Preferably, though, a said anti-reingestion means (64) for enabling air to pass therethrough form said chamber (30) to the tubing (400), and for substantially preventing entry of air therefrom back into the chamber (30), is provided at the upstream end of tubing (400), close to outlet (24).

In a tenth embodiment of the present invention, and referring to Figure 15, the air venting means (60) comprises the same structural elements as the eighth embodiment of Figure 13, with the exception of the said closed end (430) of second tubing (400), as hereinbefore described, *mutatis mutandis*. Instead of having a closed second end (430), in this aspect of the second embodiment, the second end (430") is connected to a vacuum source (450) capable of providing a suitable vacuum to the second tubing (400). The vacuum source (450) may comprise, for example, a syringe that is manually or automatically actuable, or alternatively a spring loaded bellows arrangement set to expand manually or automatically, so as to create a suction force with respect to the second tubing (400). The clamp means (480) closes the vacuum source (450) from the lower end (444) of second tubing (400) and from the rest of the first tubing (40) as well. Optionally, though, the clamp means (480) may also close the lower end (44) of the first tubing (40) from its upper portion (43), the lower portions (44), (444) also being initially in an evacuated state prior to operation of said device (10). Operation of the infusion administration set (900) is by releasing said clamp (480) and thereby opening fluid communication between said first portion (43) and said second

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portion (44) of said first tubing (40), and between the lower portion (444) the second tubing (400) and the vacuum means (450), whereupon liquid flows into the second portion (44), chamber (30) and at least part of second tubing (400) on account of the vacuum previously present and/or the vacuum provided by the vacuum source (450). The vacuum provided by the vacuum source (450), and optionally by the lower portions of the first and second tubings, (40) and (400) respectively, serves to accelerate the priming procedure, particularly when the infusion tubing comprises narrow lumens. Optionally, the device (10') may comprise said anti-reingestion means (64) for enabling air to pass therethrough form said chamber (30) to the tubing (400), and for substantially preventing entry of air therefrom back into the chamber (30), in a manner similar to that described for the first embodiment, *mutatis mutandis*.

In an eleventh embodiment of the present invention, and referring to Figure 16, the air venting means (60) is similar in some respects to that of the fifth embodiment as hereinbefore described, *mutatis mutandis*, with some differences, as will become evident. The air venting means (60) of the eleventh embodiment comprises a second tubing (500) having a first end (520) thereof connected to said bypass outlet (24) and having a second end (530) thereof connected to the drip chamber (90) at a location above the operational liquid level (92) thereof. Thus air may be diverted to said drip chamber (90) via said second tubing (500) while substantially preventing liquid from said drip chamber (90) to flow through said second tubing (500). The first tubing (40) is operatively connected to said liquid source (70) via said drip chamber (90). In this embodiment, a clamp means (155) clamps at least said first tubing (40) such as to selectively close or open fluid communication between a first portion (43) of said first tubing (40)

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comprised between said clamp (155) and said drip chamber (90), and a second portion (44) of said tubing (40) downstream of said clamp (155). Operation of the infusion administration set (900) of this embodiment is by releasing said clamp (155) and thus opening fluid communication between said first portion (44) and said second portion (43) of said first tubing (40). Liquid descends down the second portion (43), into chamber (30), and up second tubing (500) until the levels of liquid in both tubings (40), (500) are equalised, and the air comprised in these tubings is pushed out from the upper end (530) of the second tubing (500) and into the drip chamber (90). The valve means (50) is set to open under these conditions. Optionally, air may be drawn into the drip chamber (90) via a hydrophobic filter (95).

Preferably, the second tubing (500) in this embodiment is in substantially parallel and juxtaposed alignment with respect to said first tubing (40). Advantageously, at least an upstream portion (544) of said second tubing (500) is integrally connected to at least a part of said downstream portion (44) of said first tubing (40). In fact the upstream portion (544) of said second tubing (500) and said at least part of said downstream portion (44) of said first tubing (40) may be integrally formed as a double lumen tubing. Then, as with the seventh embodiment for example, the lower part of the double lumen tubing may be bifurcated to integrally or otherwise connect with the priming device (10'). Alternatively, the lower part of the double lumen tubing may connect to the housing (20') in a manner similar to that described in connection with Figure 11(a) to Figure 11(d).

Optionally, a pump (160) may be provided between the clamp (155) and the drip chamber (90). Further optionally, the device (10') may comprise said anti-reingestion means (64) for enabling air to pass therethrough form said chamber (30) to the tubing (500), and for substantially preventing entry of air

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therefrom back into the chamber (30), in a manner similar to that described for the first embodiment, *mutatis mutandis*.

According to the second aspect of the present invention, a suitable, preferably self-priming filter may be comprised in the set (900) upstream of the device (10') in a manner similar to that described with respect to the first aspect of the present invention, *mutatis mutandis*.

In all embodiments, the said priming device is made from a suitable material, particularly a medically compatible and sterilisable material, typically a suitable plastics material.

The present application also relates to a per se novel flow control device (600) for use with a double lumen tubing (660) having a figure-of-eight type of transverse cross-section, as illustrated in Figure 17(c), in which a primary tubing portion (661) is integrally joined to a secondary tubing portion (662) in parallel juxtaposed relationship thereto. The double lumen tubing comprises troughs (655) at opposite sides of the common wall between the primary tubing (661) and secondary tubing (662).

The flow control device (600) may be adapted to clamp said primary tubing (661) while leaving the said secondary tubing (662) in an unclamped state. This flow control device (600) may be of particular advantage when used in conjunction with the infusion of set of the present invention, when the said first tubing (40) thereof and the corresponding said second tubing (300), (400) or (500) (depending on the particular embodiment) are integrated in a double-lumen tubing having a figure-of-eight transverse cross-section, similar to tubing (660), for example, in which the primary tubing (661) and secondary tubing (662) thereof respectively correspond to the first tubing (40) and second tubing (300), (400) or (500).

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Thus, referring to Figures 17(a) and Figure 17(b), the flow control device (600) comprises a housing having an upper portion (620) and a lower portion (640). The upper portion (620) may comprise many of the regular features of a roller clamp, which is for use with a resilient collapsible tube, in this case the primary tubing (661) of tubing (660). The upper portion (620) comprises an elongate first body (621) comprising a first opening (622) at a first longitudinal end thereof and a second opening (623) at a second longitudinal end thereof such as to allow at least a longitudinal length of the resilient tube (40) to pass through said ends. The first body (621) defines an internal longitudinally extending channel (624) of decreasing depth from said first end to said second end, said channel (624) comprising a pair of opposed ridges (652), (654) acting as a bottom wall, and a pair of upstanding side walls (626), (627) for accommodating said tube. The ridges (652), (654) extend the full length of the roller clamp (600) and are adapted to slide in the external troughs (655) formed between the primary tubing (661) and the secondary tubing (662). The said side walls (626), (627) comprise opposed trunnion guideways (628), (629) respectively, which are substantially parallel one to another, and which are inclined with respect to said ridges (652), (654). The first body (621) further comprises a roller (630) receivable in said channel (624) and mounted on trunnions (631), (632) receivable on said trunnion guideways (628), (629), respectively, enabling said roller (630) to roll along a direction substantially parallel to said trunnion guideways (628), (629) within said body (621). At least a part of said roller (630) is accessible exteriorly of the first body (621) for enabling the roller (630) to be reversibly rolled manually at least from a first position to a second position, said roller (630) having a peripheral outer surface (635) and projecting transversely at least part of transverse width of said channel (624) for clamping a length of resilient primary tubing (661) between said peripheral outer surface and the

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ridges (652), (654) of said channel (624) opposite thereto. The lower portion (640) also comprises an elongate second body (641) comprising a first opening (642) at a first longitudinal end thereof and a second opening (643) at a second longitudinal end thereof such as to allow at least a longitudinal length of the resilient secondary tubing (662) to pass through said ends. The second body (641) defines an internal longitudinally extending channel (644) of constant depth from said first end to said second end thereof to accommodate the secondary tubing (662) when the primary tubing (661) is comprised in the first body (621).

Thus, in operation, a double-lumen tubing (660) having a primary tubing portion (661) and a secondary tubing portion (662) in substantially parallel alignment may be inserted into the roller clamp (600) such that part of the primary tubing portion (661) is accommodated in the first body (621), and a corresponding part of the secondary tubing portion (662) is accommodated in the second body (641). As the roller (630) is rolled from one end to the other end of its longitudinal travel, the primary tubing portion (661) is progressively squeezed until the lumen is closed to fluid flow, while the secondary tubing (662) is substantially unaffected, its lumen remaining open to fluid flow.

While in the foregoing description describes in detail only a few specific embodiments of the invention, it will be understood by those skilled in the art that the invention is not limited thereto and that other variations in form and details may be possible without departing from the scope and spirit of the invention herein disclosed.

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Claims: -

1. A priming device for enabling at least a portion of a first tubing operatively connected to a liquid source to be selectively primed with liquid from said source during operation of the device, comprising:-

(a) a housing defining a chamber and comprising a fluid inlet in fluid communication with a bypass outlet via said chamber, said fluid inlet adapted for operative connection with said first tubing via a first end thereof for providing fluid communication between said tubing and said chamber during operation of said device;

(b) suitable air venting means in fluid communication with said bypass outlet for enabling at least gas to be vented from said chamber during operation of said device; and

(c) valve means having a valve inlet and a valve outlet, said valve inlet adapted for providing liquid communication when open with said chamber, said valve means adapted for enabling liquid communication between said chamber and said valve outlet to be selectively prevented or allowed during operation of said device, according to predetermined conditions.

2. A device as claimed in claim 1, wherein said predetermined conditions comprise allowing or preventing fluid communication between said chamber and said valve outlet, according to whether or not said chamber is substantially filled with said liquid.

3. A device as claimed in claim 2, wherein said valve is adapted for allowing communication between the chamber and the valve outlet when the differential fluid pressure therebetween exceeds a predetermined value.

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4. A device as claimed in claim 3, wherein said fluid pressure is provided by liquid pressure of a liquid comprised in said chamber during operation of said device.

5. A device as claimed in claim 4, wherein said predetermined fluid pressure differential is provided by a predetermined head of liquid comprised in said tubing during operation of said device.

6. A device as claimed in claim 3, wherein said valve means comprises a suitable duckbill valve.

7. A device as claimed in claim 3, wherein said valve means comprises a suitable diaphragm valve.

8. A device as claimed in claim 3, wherein said valve means comprises a suitable ball valve.

9. A device as claimed in claim 3, wherein said valve means is externally actuable for allowing communication between the chamber and the valve outlet when required by a user.

10. A device as claimed in claim 1, wherein said device further comprises a connection means in fluid communication with said valve outlet, said connection means being adapted for operative connection to a suitable patient interface.

11. A device as claimed in claim 10, wherein said patient interface comprises a suitable cannula that is adapted for introduction into the body of a patient.

12. A device as claimed in claim 1, wherein said air venting means comprises a suitable means for enabling air to pass therethrough form said

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chamber to an outside thereof, but substantially prevents entry of air therethrough from said outside the device into the chamber, said suitable means being connected in near to or at said bypass outlet.

13. A device as claimed in claim 12, wherein said air venting means comprises a suitable one-way valve arrangement.

14. A device as claimed in claim 12, wherein said air venting means comprises a suitable hydrophobic filter arrangement.

15. A device as claimed in claim 1, wherein said air venting means comprises a second tubing of a predetermined length and having a first end thereof connected to said bypass outlet and having a second end thereof connected to a suitable hydrophobic filter to provide fluid communication between said filter and said bypass outlet, such as to enable gas to be diverted to an outside of said device from said chamber, while preventing said liquid from being similarly diverted.

16. A device as claimed in claim 1, wherein said air venting means comprises a second tubing of a predetermined length and having a first end thereof connected to said bypass outlet and having a second end thereof closed, and further comprising a clamp means to clamp at least said second tubing such as to close fluid communication between a first portion of said second tubing downstream of said clamp to a second portion of said tubing upstream of said clamp, wherein said first portion of said second tubing is in a substantially evacuated state prior to operation of said device, wherein operation of said device is by releasing said clamp and opening fluid communication between said second portion of said first tubing and said chamber via said first portion.

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17. A device as claimed in claim 1, wherein said liquid source comprises suitable drip chamber and a clamp means, wherein said first tubing is operatively connected to said liquid source via said drip chamber, said clamp means adapted to clamp at least said first tubing such as to selectively close or open fluid communication between a first portion of said first tubing comprised between said clamp and said drip chamber, to a second portion of said tubing downstream of said clamp, wherein said air venting means comprises a second tubing of a predetermined length and having a first end thereof connected to said bypass outlet and having a second end thereof connectable to said drip chamber at a location above the operational liquid level of the drip chamber such as to enable gas to be diverted to said drip chamber via said second tubing while substantially preventing liquid from said drip chamber to flow through said second tubing, wherein operation of said device is by releasing said clamp means and opening fluid communication between said first portion and said second portion of said first tubing.

18. A device as claimed in claim 1, wherein said air venting means comprises a second tubing having a first end thereof connected to said bypass outlet and having a second end thereof operatively connected to a suitable vacuum source, and further comprising a clamp means to clamp at least said second tubing such as to close fluid communication between a first portion of said second tubing upstream of said clamp and including the vacuum source to a second portion of said second tubing downstream of said clamp, wherein operation of said device is by releasing said clamp and opening fluid communication between said first tubing and said vacuum source.

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19. A device as claimed in claim 1, further comprising a suitable filter having a liquid inlet and a liquid outlet, said liquid outlet being in open communication with said fluid inlet of said device, and wherein said fluid inlet is adapted for connection to said first tubing via said liquid inlet of said filter.

20. A device as claimed in claim 19, wherein said filter is an air eliminating filter.

21. A device as claimed in claim 20, wherein said filter is integrally connected to said fluid inlet.

22. A device as claimed in claim 20, wherein said filter is removably connected to said fluid inlet by means of suitable connectors comprised in said liquid outlet and aid fluid inlet.

23. A device as claimed in claim 20, wherein said filter comprises a length of tubing providing communication between said liquid outlet and said fluid inlet such as to enable the said filter to be displaced vertically above the said device by a predetermined height.

24. A device as claimed in claim 23, wherein said predetermined height is less than the head of liquid required to open said valve means.

25. A device as claimed in any one of claims 15 to 24, further comprising suitable one-way means for enabling air to pass therethrough form said chamber to said second tubing, and for substantially preventing entry of air therethrough from said second tubing into the chamber, said suitable means.

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26. A device as claimed in claim 25, wherein said one-way means comprises a suitable one-way valve arrangement.

27. A device as claimed in claim 25, wherein said one-way means comprises a suitable hydrophobic filter arrangement.

28. A device as claimed in any one of claims 15 to 24, wherein said second tubing is adapted for substantially parallel and juxtaposed alignment with respect to said first tubing when said device is connected to said first tubing.

29. A device as claimed in claim 28, wherein said second tubing is adapted for substantially parallel and juxtaposed alignment with respect to said first tubing by comprising suitable clamping means whereby to enable at least an upstream portion of said second tubing to be connected to an at least a downstream portion of said first tubing.

30. A device as claimed in any one of claims 1 to 24, wherein said device is adapted for use with a medical infusion system, said medical infusion system comprising said a first tubing operatively connected to said liquid source, and wherein said fluid inlet comprises a suitable connector for connecting with a compatible connector comprised at a downstream end of said infusion administration set.

31. A device as claimed in claim 30, wherein said medical infusion system comprises any one of an infusion administration set, a dialysis blood system or a bypass blood system.

32. A self priming infusion administration set comprising:-

(a) first tubing means having a first end and a second end, said second end being adapted for operative connection to a suitable liquid source;

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(b) a priming device as claimed in any one of claims 1 to 24, said fluid inlet being connected to said first end of said first tubing, wherein said device is adapted to connection to a patient via suitable patient interface means.

33. A set as claimed in claim 32, wherein said device is adapted for connection to a patient by comprising suitable connection means in fluid communication with said valve outlet, said connection means being adapted for operative connection to said patient interface means.

34. A set as claimed in claim 33, wherein said patient interface comprises a suitable cannula that is adapted for introduction into the body of a patient

35. A set as claimed in claim 32, further comprising said source of liquid operatively connected to said second end of said first tubing.

36. A set as claimed in claim 35, further comprising a suitable drip chamber and a clamp means, wherein said first tubing is operatively connected to said liquid source via said drip chamber, said clamp means adapted to clamp at least said first tubing such as to selectively close or open fluid communication between a first portion of said first tubing comprised between said clamp and said drip chamber, to a second portion of said tubing downstream of said clamp.

37. A set as claimed in claim 36, further comprising a suitable roller clamp operatively connected to said first tubing and adapted for regulating the flow from said liquid source via said first tubing.

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38. A set as claimed in claim 37, further comprising a suitable pump operatively connected to said first tubing and adapted for regulating the flow from said liquid source via said first tubing.

39. A set as claimed in claim 32, wherein said air venting means comprises a suitable means for enabling air to pass therethrough form said chamber to an outside thereof, and for substantially preventing entry of air therethrough from said outside the device into the chamber, said suitable means being connected in near to or at said bypass outlet.

40. A set as claimed in claim 39, wherein said air venting means comprises a suitable one-way valve arrangement.

41. A set as claimed in claim 39, wherein said air venting means comprises a suitable hydrophobic filter arrangement.

42. A set as claimed in claim 32, wherein said air venting means comprises a second tubing of a predetermined length and having a first end thereof connected to said bypass outlet and having a second end thereof connected to a suitable hydrophobic filter to provide fluid communication between said filter and said bypass outlet, such as to enable gas to be diverted to an outside of said device from said chamber, while preventing said liquid from being similarly diverted.

43. A set as claimed in claim 42, further comprising suitable one-way means for enabling air to pass therethrough form said chamber to said second tubing, and for substantially preventing entry of air therethrough from said second tubing into the chamber, said suitable means.

44. A set as claimed in claim 43, wherein said one-way means comprises a suitable one-way valve arrangement.

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45. A set as claimed in claim 43, wherein said one-way means comprises a suitable hydrophobic filter arrangement.

46. A set as claimed in claim 42, wherein at least an upstream portion of said second tubing is integrally connected to an at least a downstream portion of said first tubing.

47. A set as claimed in claim 46, wherein said upstream portion of said second tubing and said downstream portion of said first tubing are formed as a double lumen tubing.

48. A set as claimed in claim 32, wherein said air venting means comprises a second tubing of a predetermined length and having a first end thereof connected to said bypass outlet and having a second end thereof connected to a suitable one-way valve to provide fluid communication between said one-way valve and said bypass outlet, such as to enable gas to be diverted to an outside of said device from said chamber, while preventing said liquid from being similarly diverted.

49. A set as claimed in claim 48, further comprising suitable one-way means for enabling air to pass therethrough form said chamber to said second tubing, and for substantially preventing entry of air therethrough from said second tubing into the chamber, said suitable means.

50. A set as claimed in claim 49, wherein said one-way means comprises a suitable second one-way valve arrangement.

51. A set as claimed in claim 49, wherein said one-way means comprises a suitable hydrophobic filter arrangement.

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52. A set as claimed in claim 48, wherein at least an upstream portion of said second tubing is integrally connected to an at least a downstream portion of said first tubing.

53. A set as claimed in claim 52, wherein said upstream portion of said second tubing and said downstream portion of said first tubing are formed as a double lumen tubing.

54. A set as claimed in claim 32, wherein said air venting means comprises a second tubing having a first end thereof connected to said bypass outlet and having a closed second end, and further comprising a clamp means to clamp at least said first tubing such as to close fluid communication between a first portion of said first tubing upstream of said clamp to a second portion of said tubing downstream of said clamp, wherein said second portion of said first tubing, said chamber and said second tubing comprise are in an evacuated state prior to operation of said device, wherein operation of said device is by releasing said clamp and opening fluid communication between said first portion and said second portion of said first tubing.

55. A set as claimed in claim 54, wherein said clamp simultaneously clamps said first tubing and said second tubing at least prior to operation of said device.

56. A set as claimed in claim 54, further comprising suitable one-way means for enabling air to pass therethrough form said chamber to said second tubing, and for substantially preventing entry of air therethrough from said second tubing into the chamber, said suitable means.

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57. A set as claimed in claim 56, wherein said one-way means comprises a suitable second one-way valve arrangement.

58. A set as claimed in claim 56, wherein said one-way means comprises a suitable hydrophobic filter arrangement.

59. A set as claimed in claim 54, wherein at least an upstream portion of said second tubing is integrally connected to an at least a downstream portion of said first tubing.

60. A set as claimed in claim 59, wherein said upstream portion of said second tubing and said downstream portion of said first tubing are formed as a double lumen tubing.

61. A set as claimed in claim 32, wherein said air venting means comprises a second tubing having a first end thereof connected to said bypass outlet and having a second end thereof connected to a drip chamber at a location above the operational liquid level thereof such as to enable gas to be diverted to said drip chamber via said second tubing while substantially preventing liquid from said drip chamber to flow through said second tubing, said first tubing being operatively connected to said liquid source via said drip chamber and further comprising a clamp means to clamp at least said first tubing such as to selectively close or open fluid communication between a first portion of said first tubing comprised between said clamp and said drip chamber, to a second portion of said tubing downstream of said clamp, wherein operation of said device is by releasing said clamp and opening fluid communication between said first portion and said second portion of said first tubing.

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62. A set as claimed in claim 61, further comprising suitable one-way means for enabling air to pass therethrough form said chamber to said second tubing, and for substantially preventing entry of air therethrough from said second tubing into the chamber, said suitable means.

63. A set as claimed in claim 62, wherein said one-way means comprises a suitable second one-way valve arrangement.

64. A set as claimed in claim 62, wherein said one-way means comprises a suitable hydrophobic filter arrangement.

65. A set as claimed in claim 61, wherein at least an upstream portion of said second tubing is integrally connected to an at least a downstream portion of said first tubing.

66. A set as claimed in claim 65, wherein said upstream portion of said second tubing and said downstream portion of said first tubing are formed as a double lumen tubing.

67. A set as claimed in claim 32, wherein said the air venting means comprises a second tubing having a first end thereof connected to said bypass outlet and having a second end thereof operatively connected to a suitable vacuum source, and further comprising a clamp means to clamp at least said second tubing such as to close fluid communication between a first portion of said second tubing upstream of said clamp and including the vacuum source to a second portion of said second tubing downstream of said clamp, wherein said second portion of said first tubing, said chamber and said second tubing comprise are in fluid communication, wherein operation of said device is by releasing said clamp and opening fluid communication between said first tubing and said vacuum source.

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68. A set as claimed in claim 67, wherein said clamp simultaneously clamps said first tubing and said second tubing at least prior to operation of said device.

69. A set as claimed in claim 67, further comprising suitable one-way means for enabling air to pass therethrough form said chamber to said second tubing, and for substantially preventing entry of air therethrough from said second tubing into the chamber, said suitable means.

70. A set as claimed in claim 69, wherein said one-way means comprises a suitable second one-way valve arrangement.

71. A set as claimed in claim 69, wherein said one-way means comprises a suitable hydrophobic filter arrangement.

72. A set as claimed in claim 68, wherein at least an upstream portion of said second tubing is integrally connected to an at least a downstream portion of said first tubing.

73. A set as claimed in claim 72, wherein said upstream portion of said second tubing and said downstream portion of said first tubing are formed as a double lumen tubing.

74. A set as claimed in claim 32, wherein said first tubing is integrally connected to said fluid inlet.

75. A set as claimed in claim 32, wherein said first tubing is connected to said fluid inlet via suitable connectors comprised at said fluid inlet and said first end of said first tubing.

76. A set as claimed in claim 33, wherein said liquid source comprises suitable drip chamber and a clamp means, wherein said first tubing is

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operatively connected to said liquid source via said drip chamber, said clamp means adapted to clamp at least said first tubing such as to selectively close or open fluid communication between a first portion of said first tubing comprised between said clamp and said drip chamber, to a second portion of said tubing downstream of said clamp, wherein said air venting means comprises a second tubing of a predetermined length and having a first end thereof connected to said bypass outlet and having a second end thereof connectable to said drip chamber at a location above the operational liquid level of the drip chamber such as to enable gas to be diverted to said drip chamber via said second tubing while substantially preventing liquid from said drip chamber to flow through said second tubing, wherein operation of said device is by releasing said clamp means and opening fluid communication between said first portion and said second portion of said first tubing.

77. A set as claimed in claim 76, further comprising suitable one-way means for enabling air to pass therethrough form said chamber to said second tubing, and for substantially preventing entry of air therethrough from said second tubing into the chamber, said suitable means.

78. A set as claimed in claim 77, wherein said one-way means comprises a suitable second one-way valve arrangement.

79. A set as claimed in claim 77, wherein said one-way means comprises a suitable hydrophobic filter arrangement.

80. A set as claimed in claim 76, wherein at least an upstream portion of said second tubing is integrally connected to an at least a downstream portion of said first tubing.

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81. A set as claimed in claim 80, wherein said upstream portion of said second tubing and said downstream portion of said first tubing are formed as a double lumen tubing.

82. A substantially completely self priming medical infusion system comprising:-

(c) first tubing means having a first end and a second end, said second end being adapted for operative connection to a suitable liquid source;

(d) a priming device as claimed in any one of claims 1 to 24, said fluid inlet being connected to said first end of said first tubing, wherein said priming device is adapted to connection to a patient's vascular system via suitable patient interface means.

83. A self priming medical infusion system as claimed in claim 82, wherein said medical infusion system comprises a dialysis blood system.

84. A self priming medical infusion system as claimed in claim 82, wherein said medical infusion system comprises a bypass blood system.

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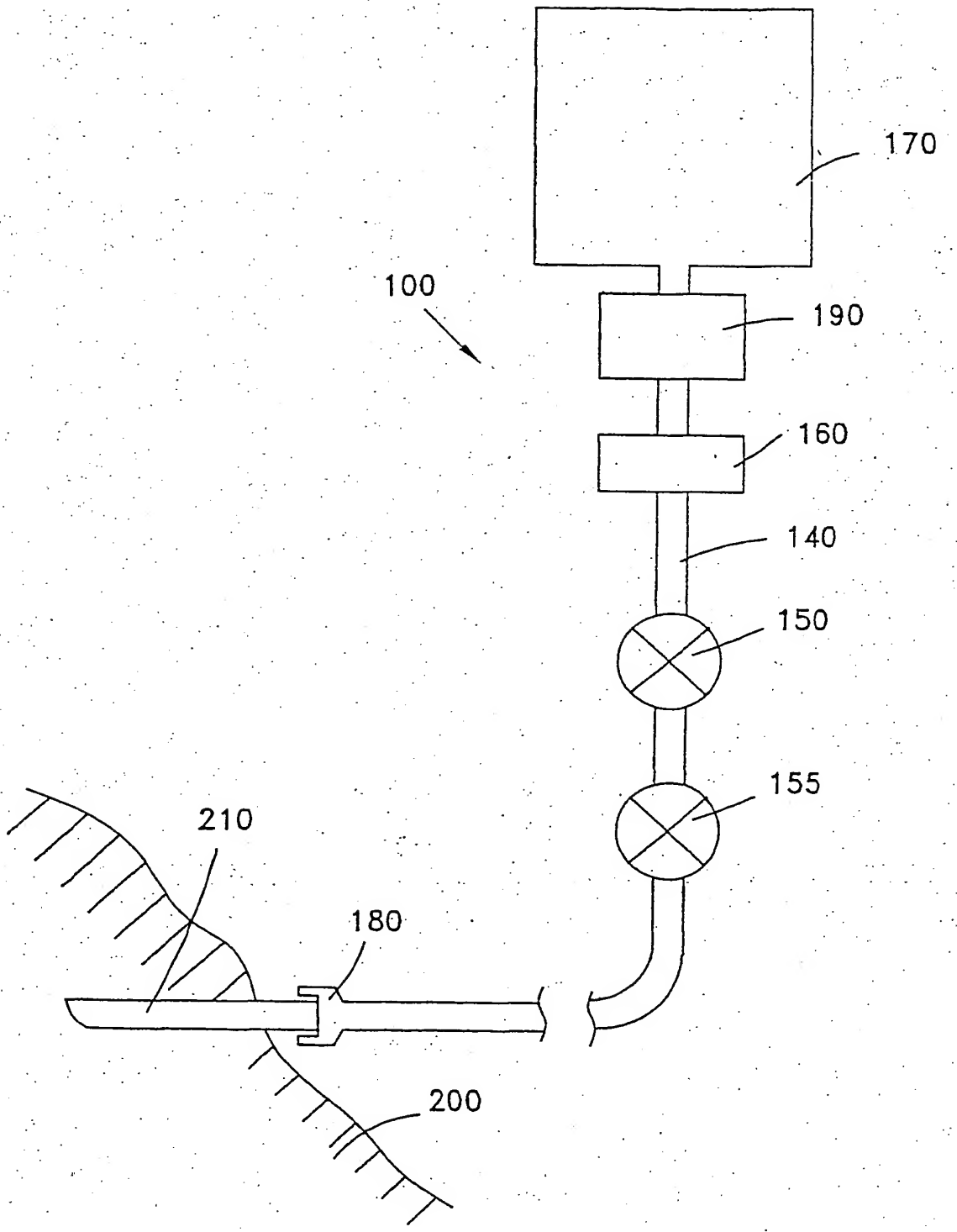

Fig. 1

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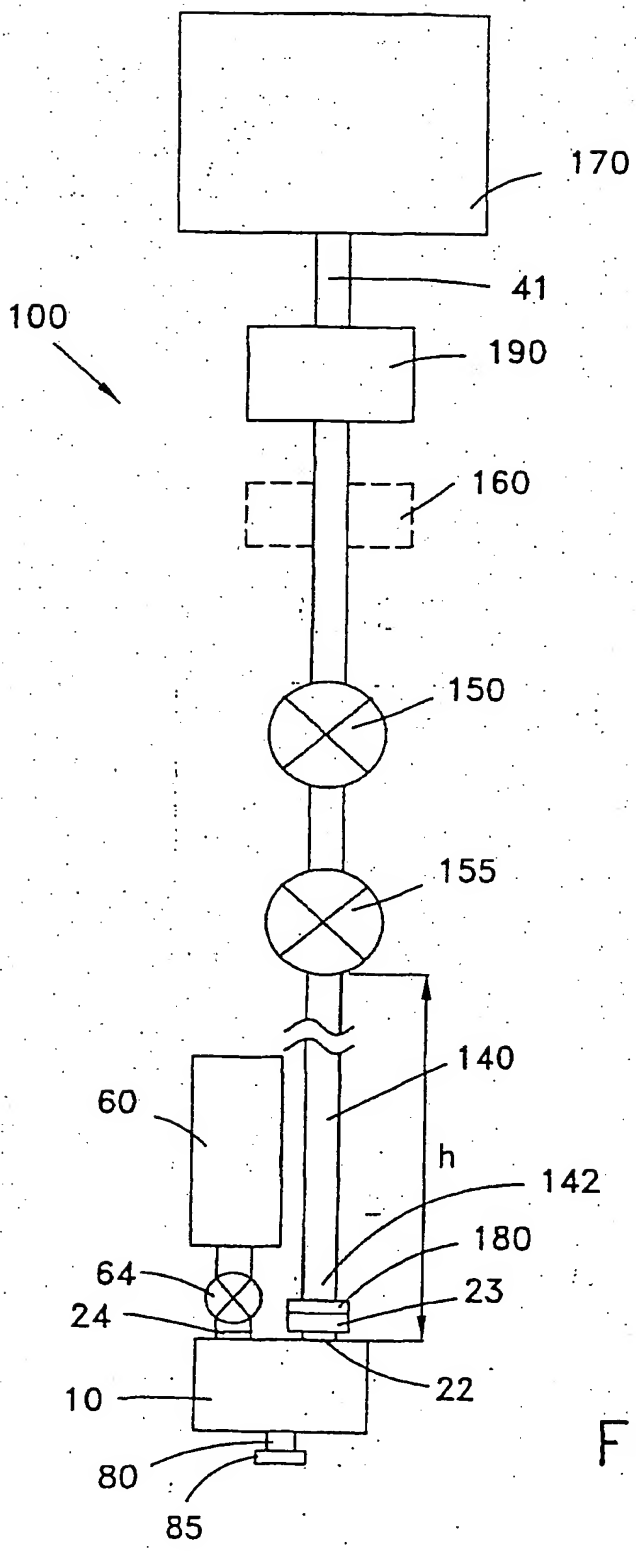

Fig. 2

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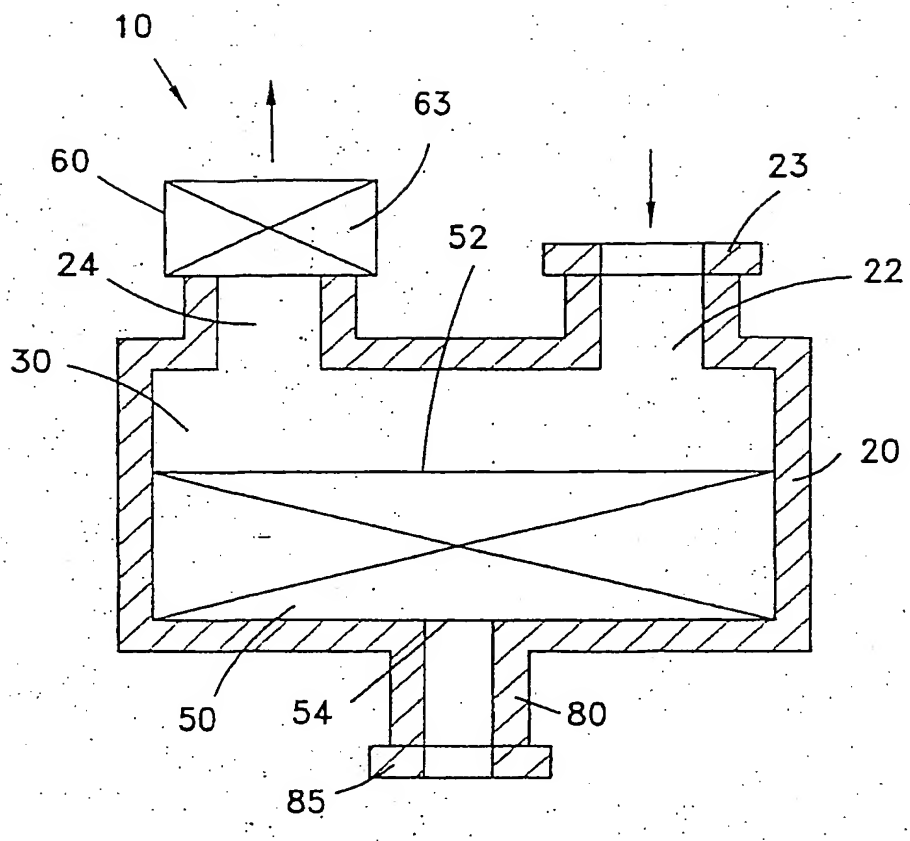

Fig. 3(a)

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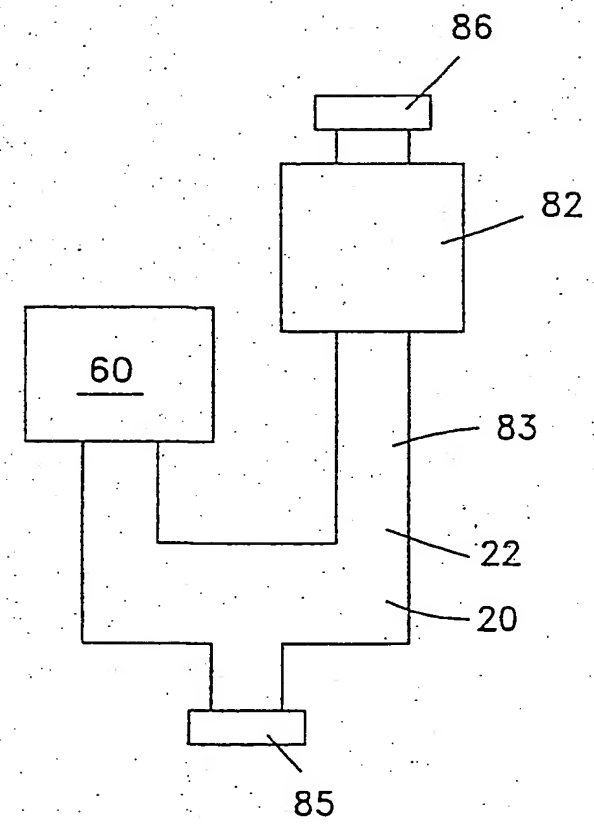

Fig. 3(b)

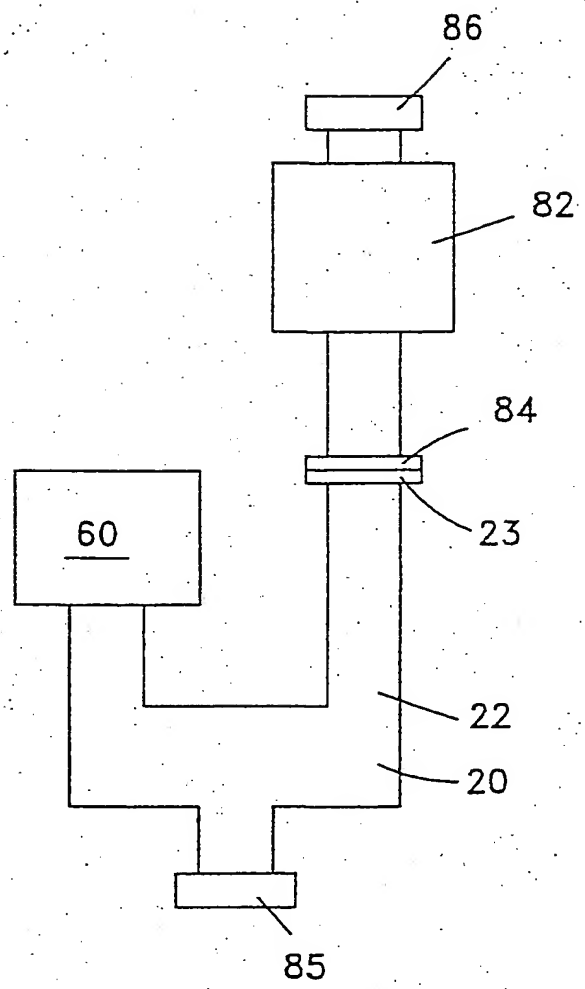

Fig. 3(c)

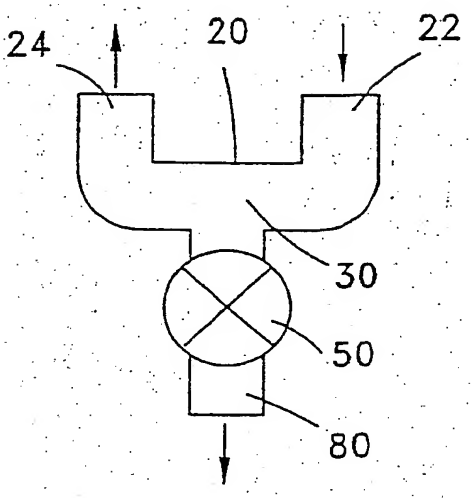

Fig. 4(a)

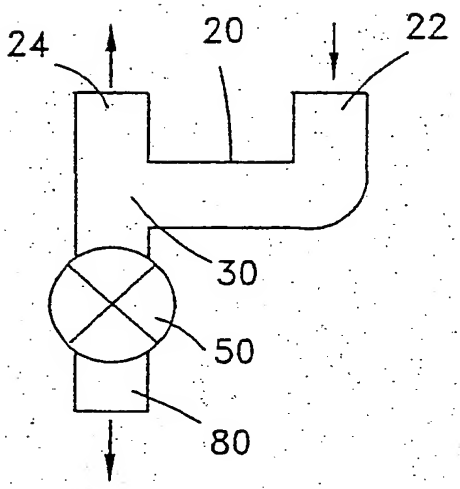

Fig. 4(b)

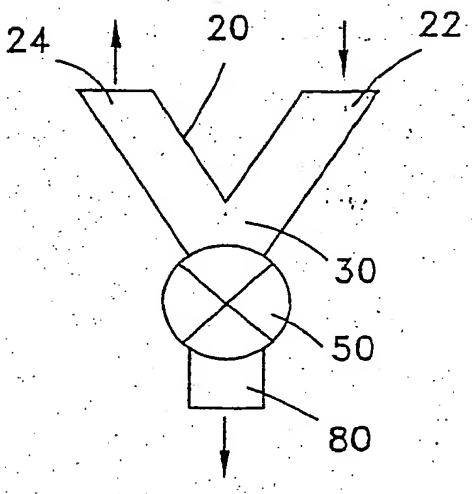

Fig. 4(c)

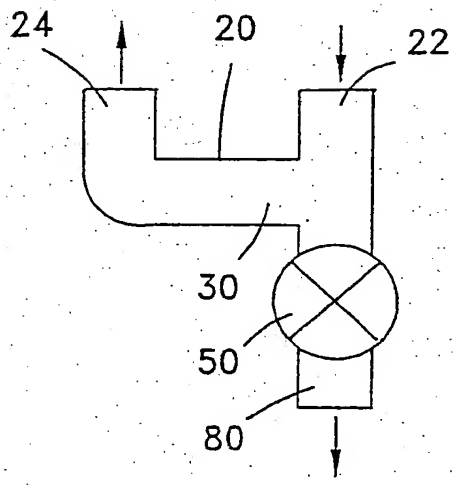

Fig. 4(d)

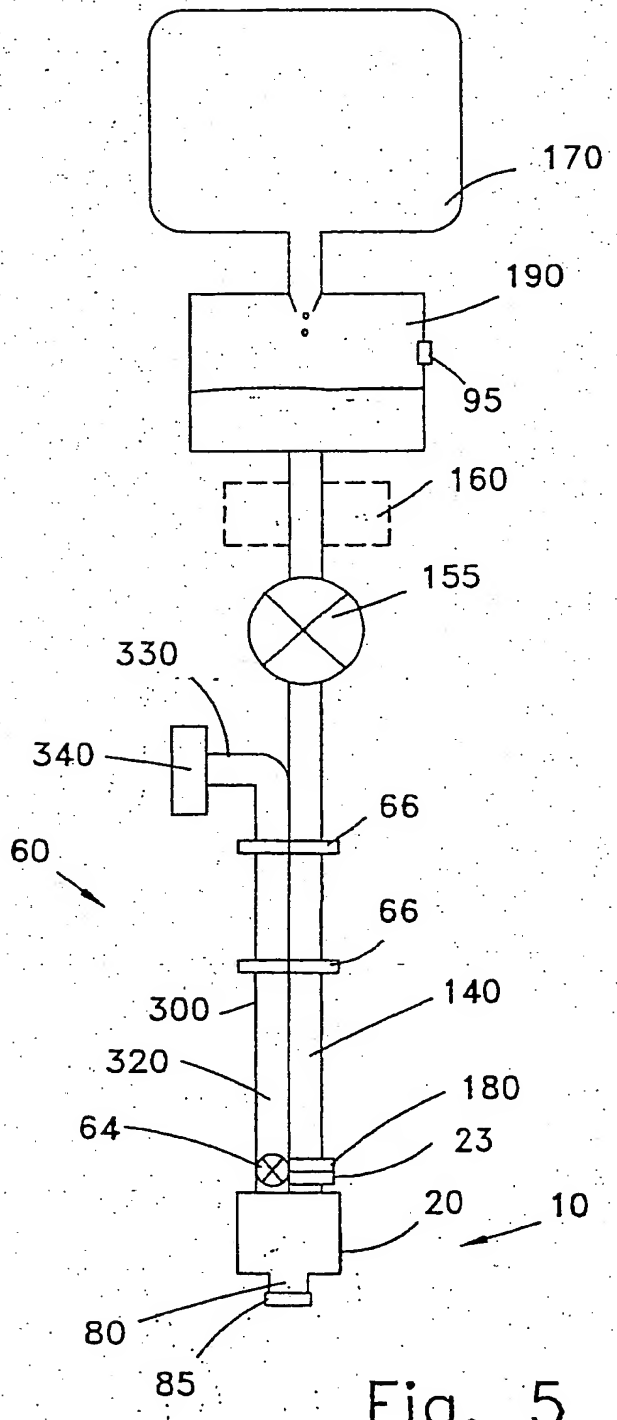

Fig. 5

BNSDOCID: <WO _0191829A2_I_>

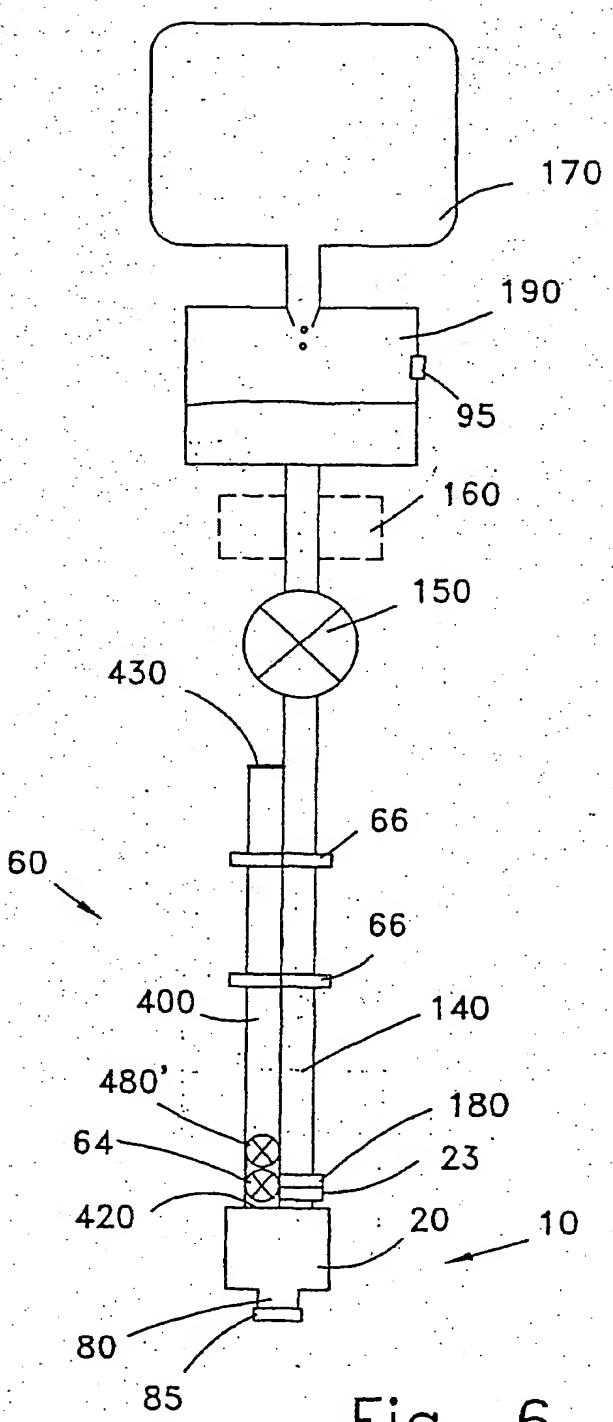

Fig. 6

BNSDOCID: <WO_ 0191829A2 I >

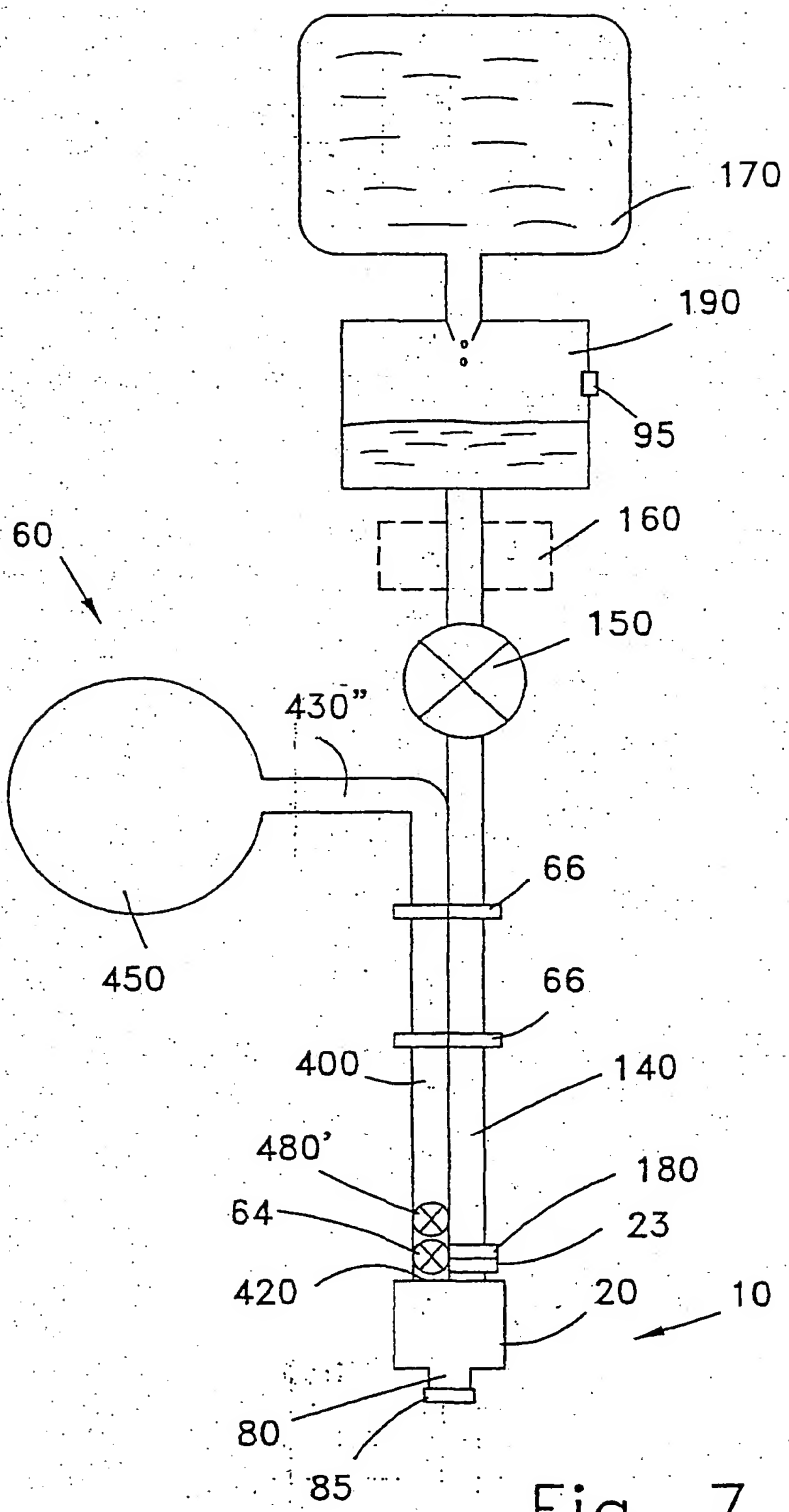

Fig. 7

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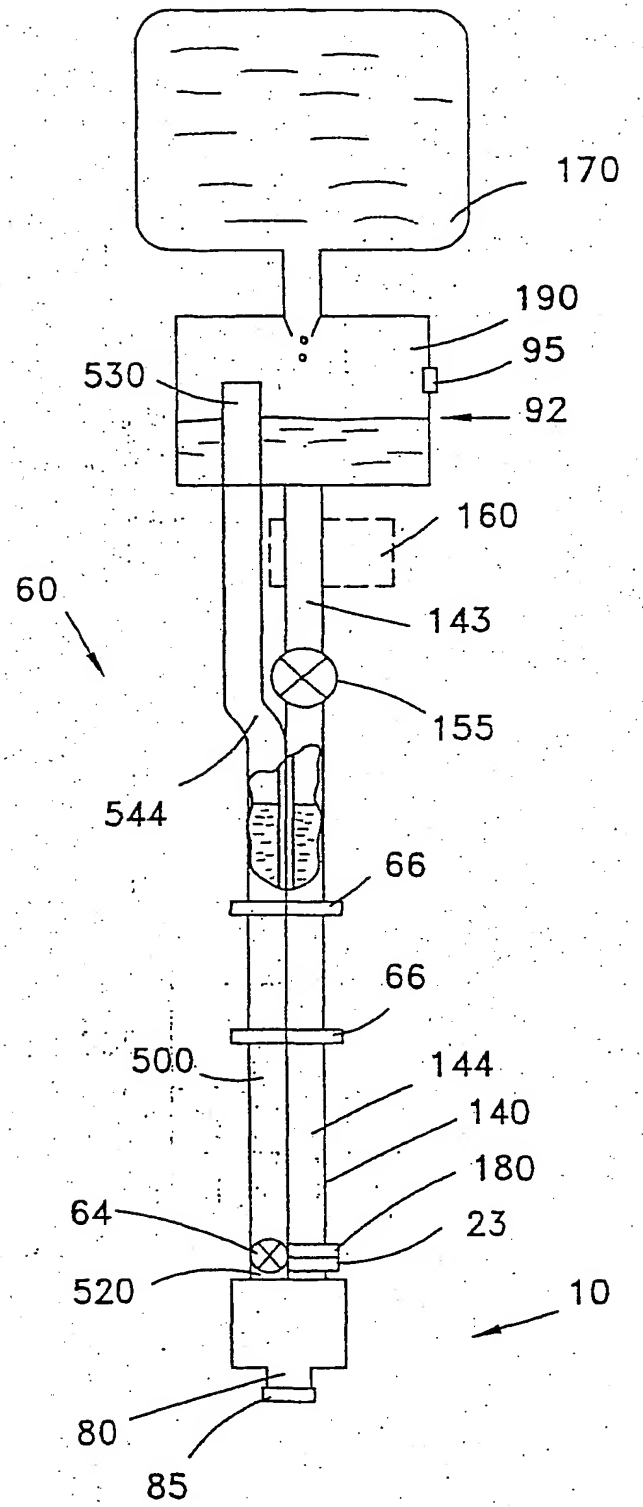

Fig. 8

BNSDOCID: <WO 0191829A2_I_>

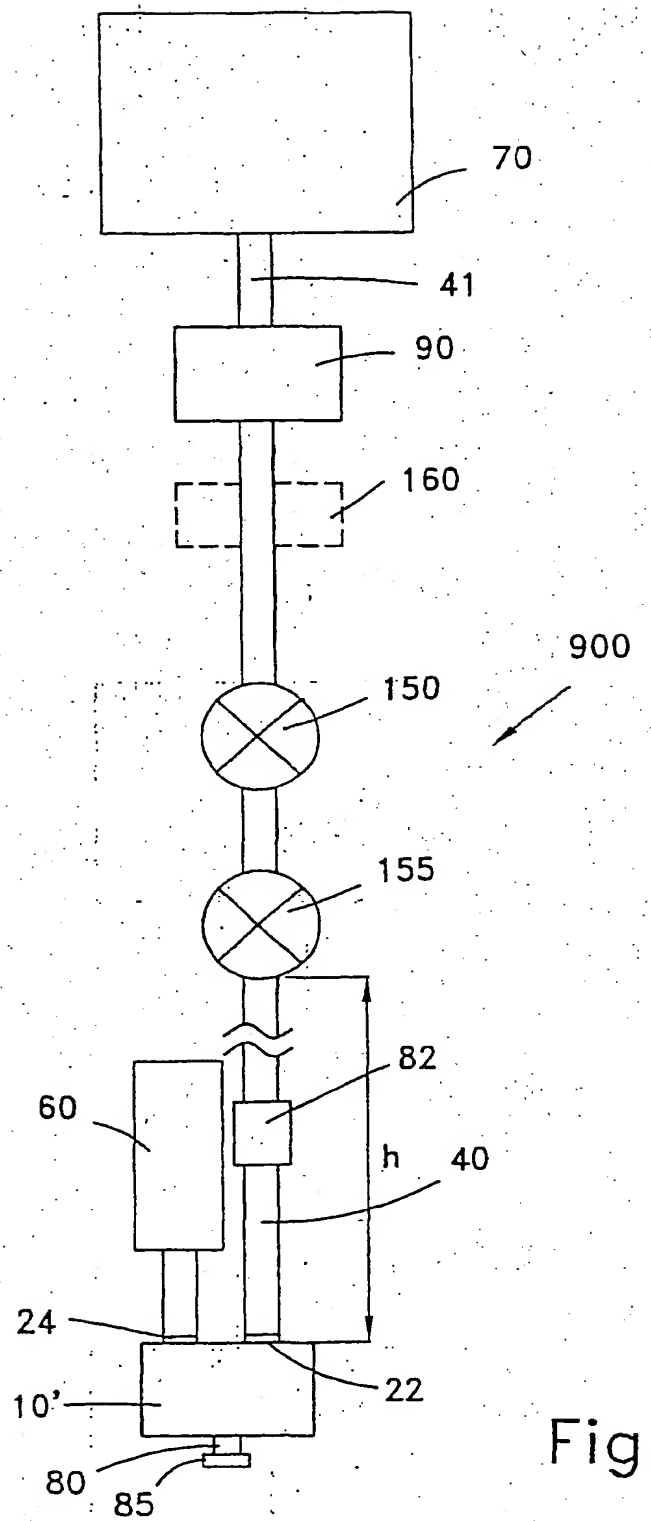

Fig. 9

BNSDOCID: <WO___0191829A2_I_>

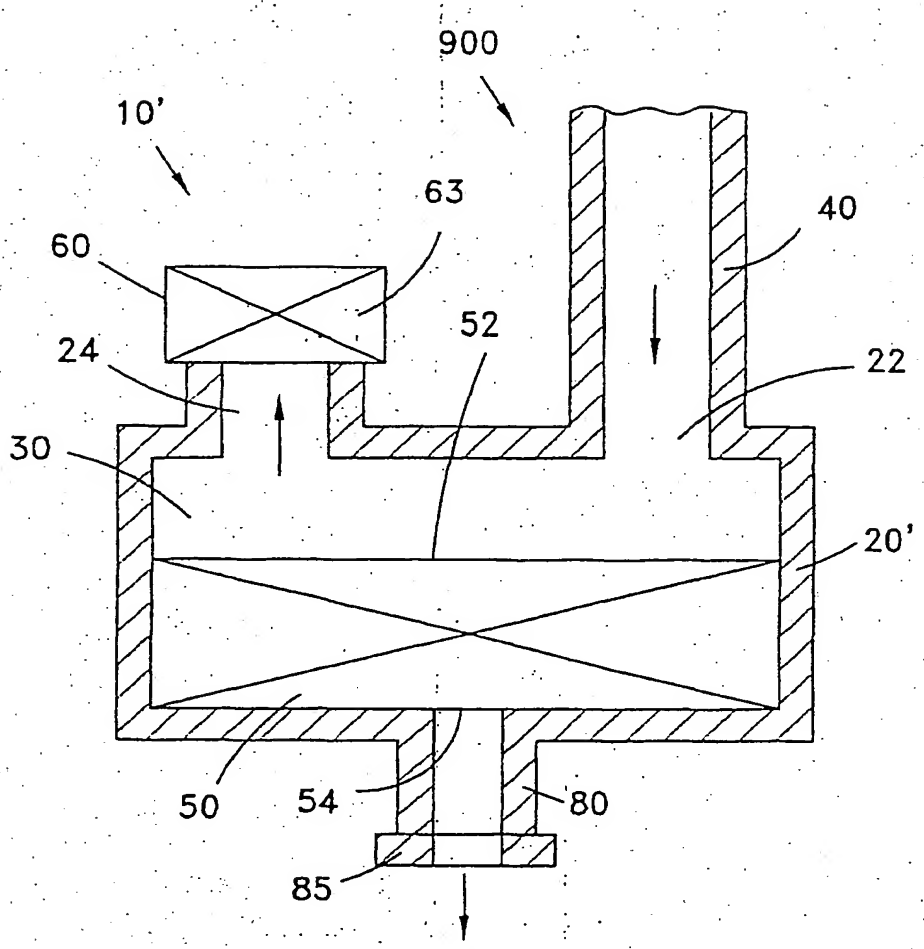

Fig. 10

BNSDOCID: <WO 0191829A2 I >

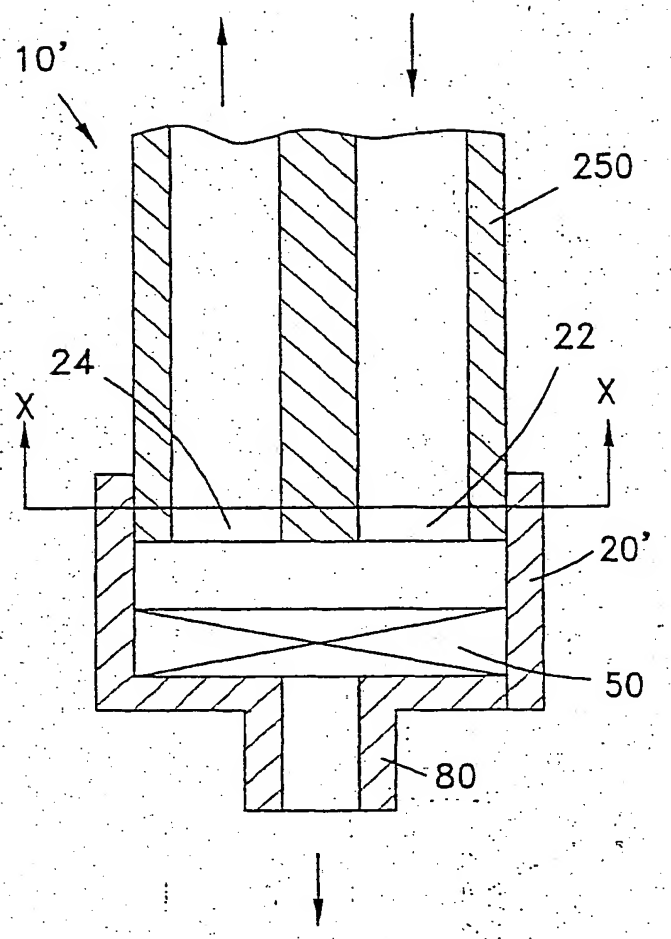

Fig. 11(a)

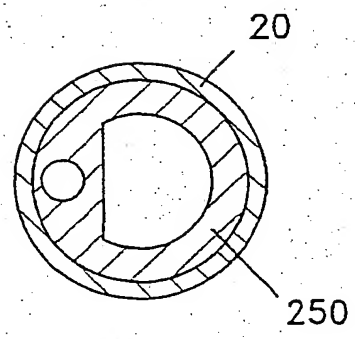

Fig. 11(c)

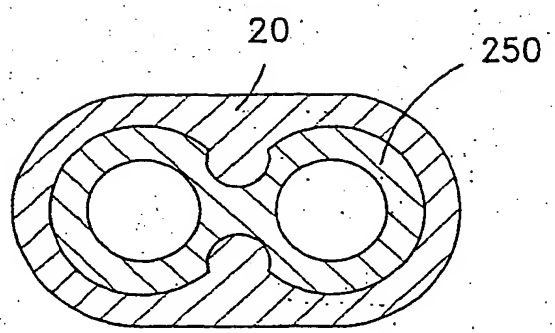

Fig. 11(b)

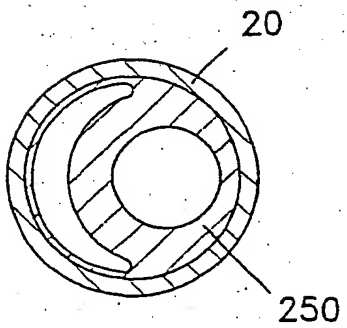

Fig. 11(d)

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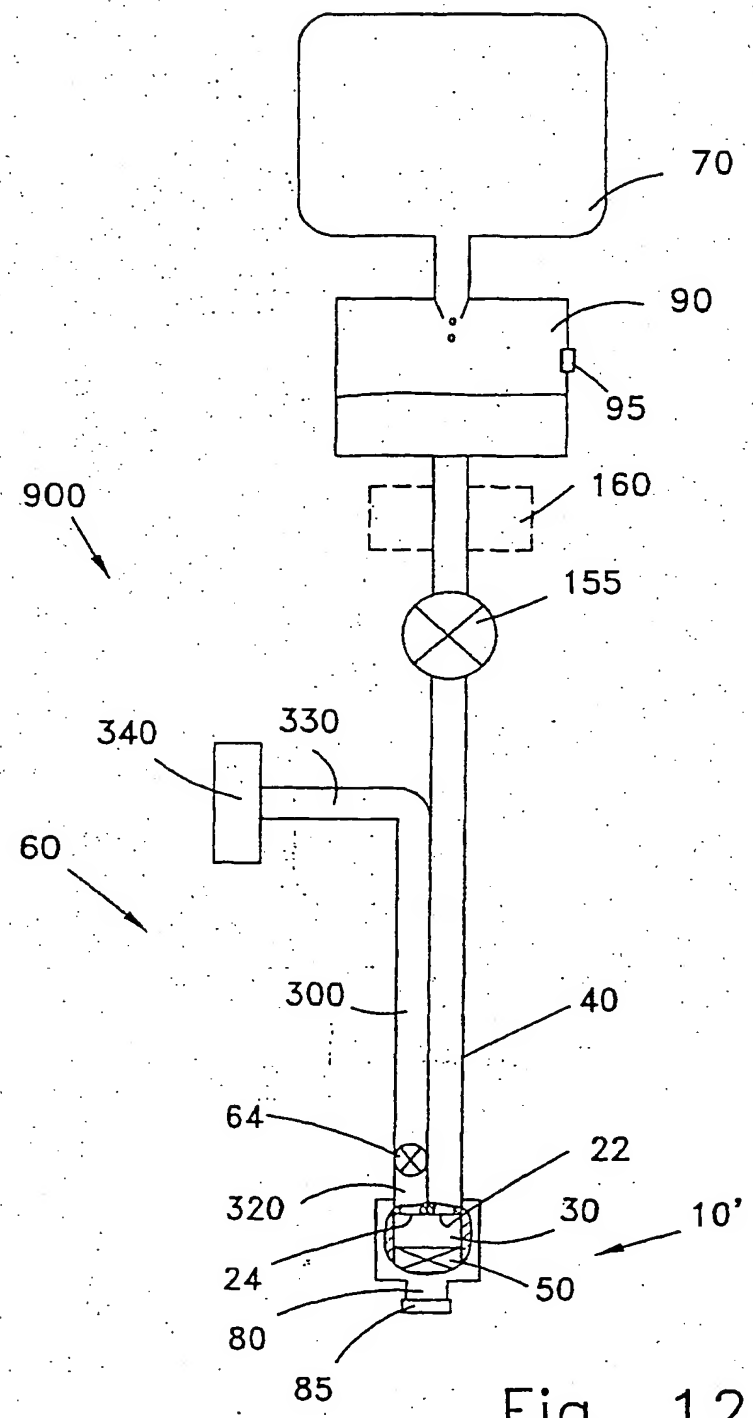

Fig. 12

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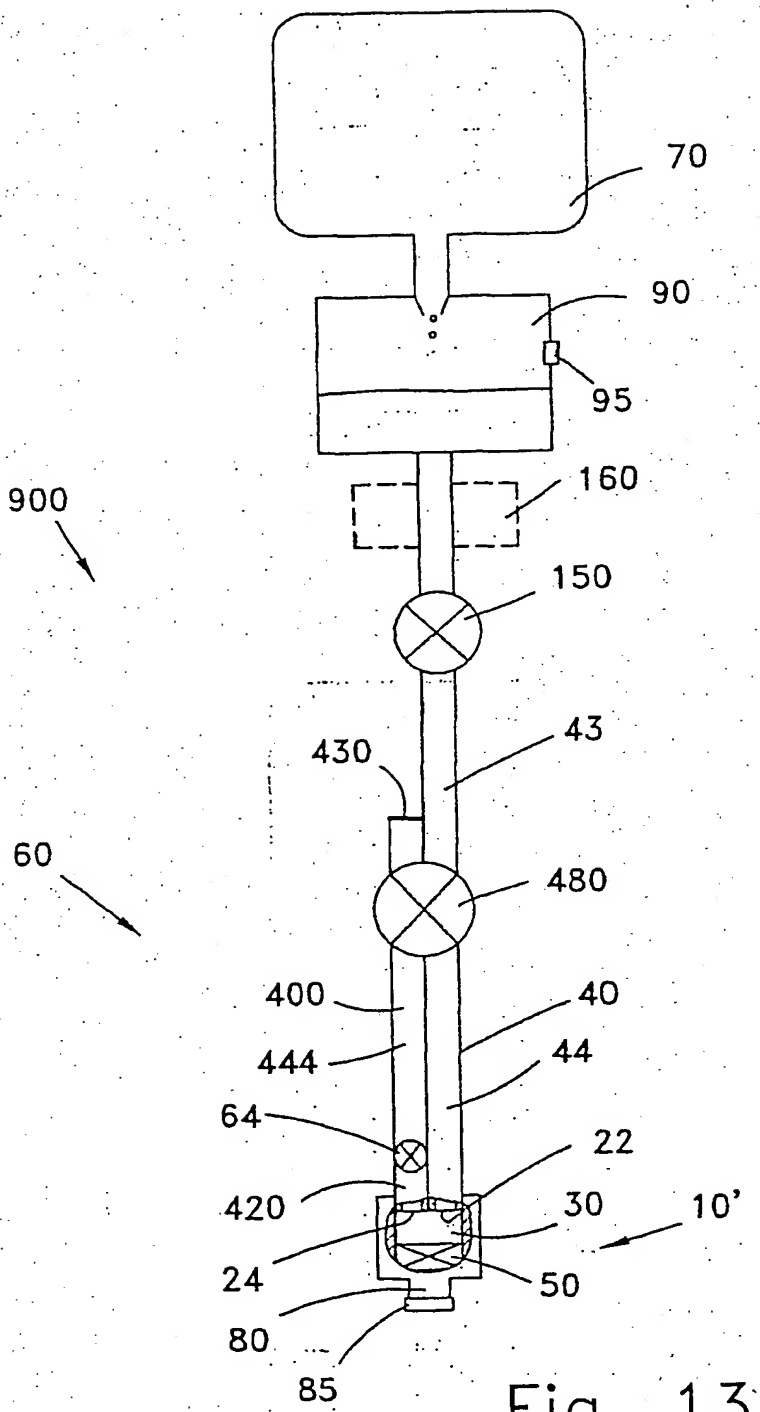

Fig. 13

BNSDOCID: <WO 0191829A2_I_>

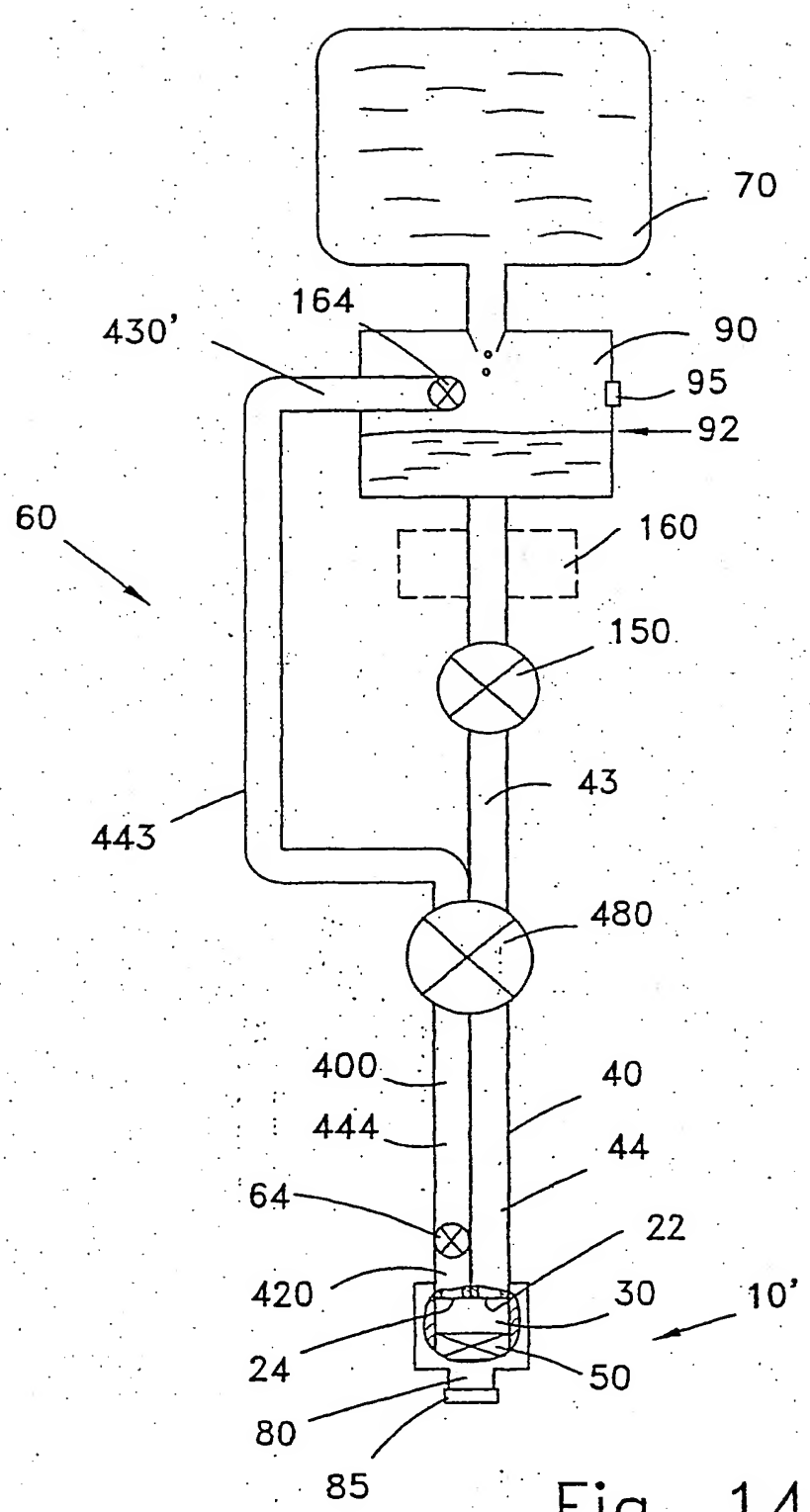

Fig. 14

BNSDOCID: <WO 0191829A2 I >

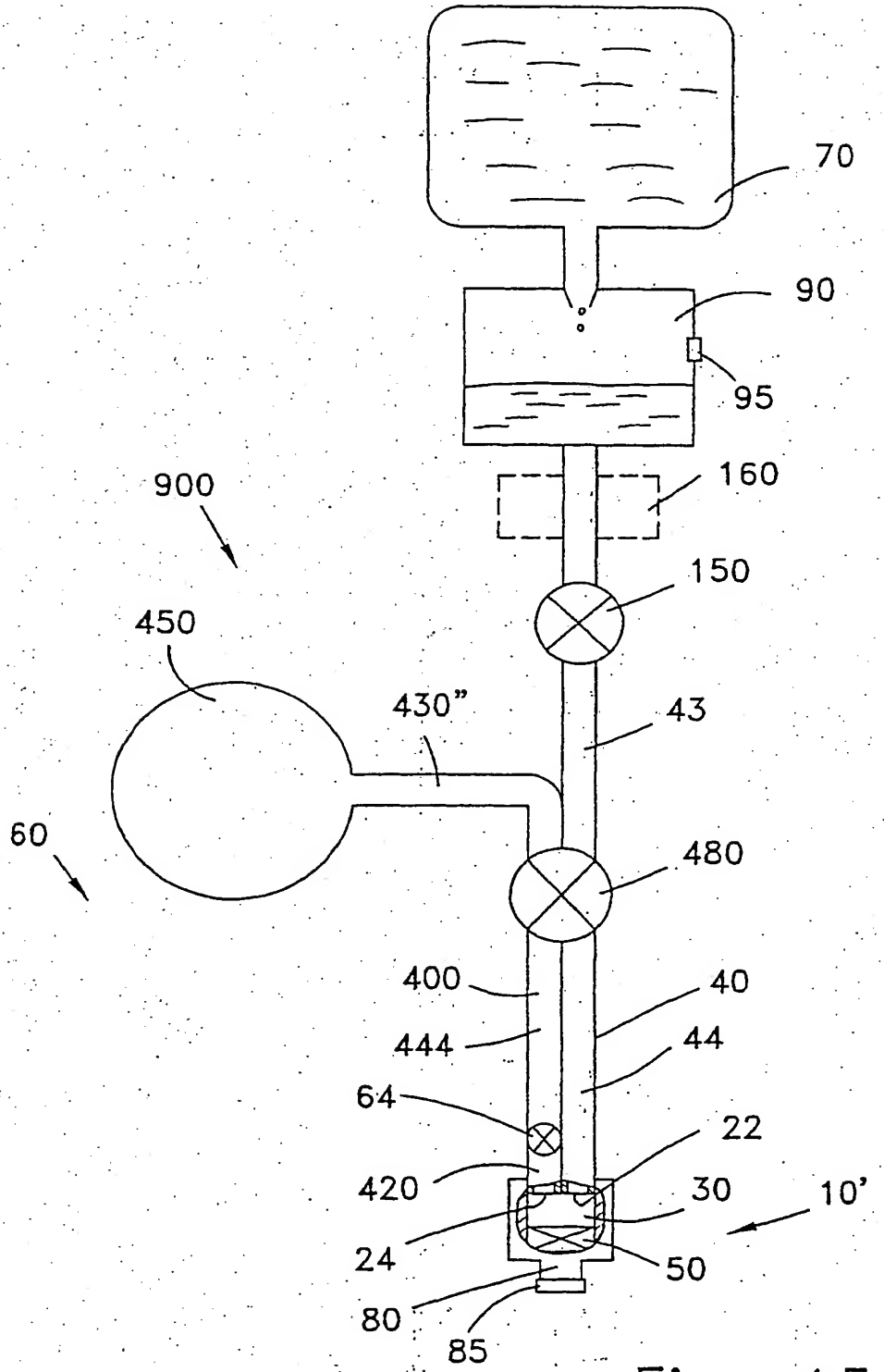

Fig. 15

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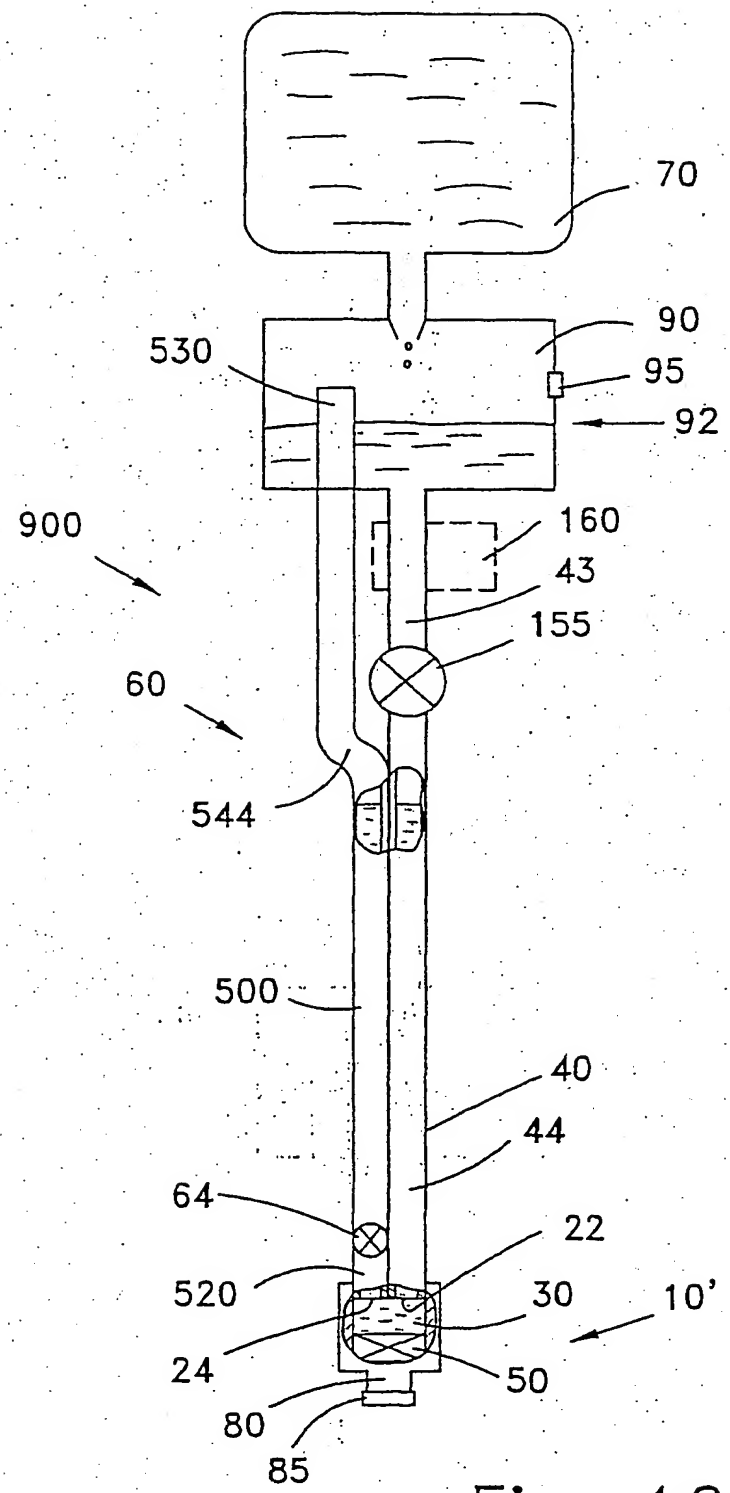

Fig. 16

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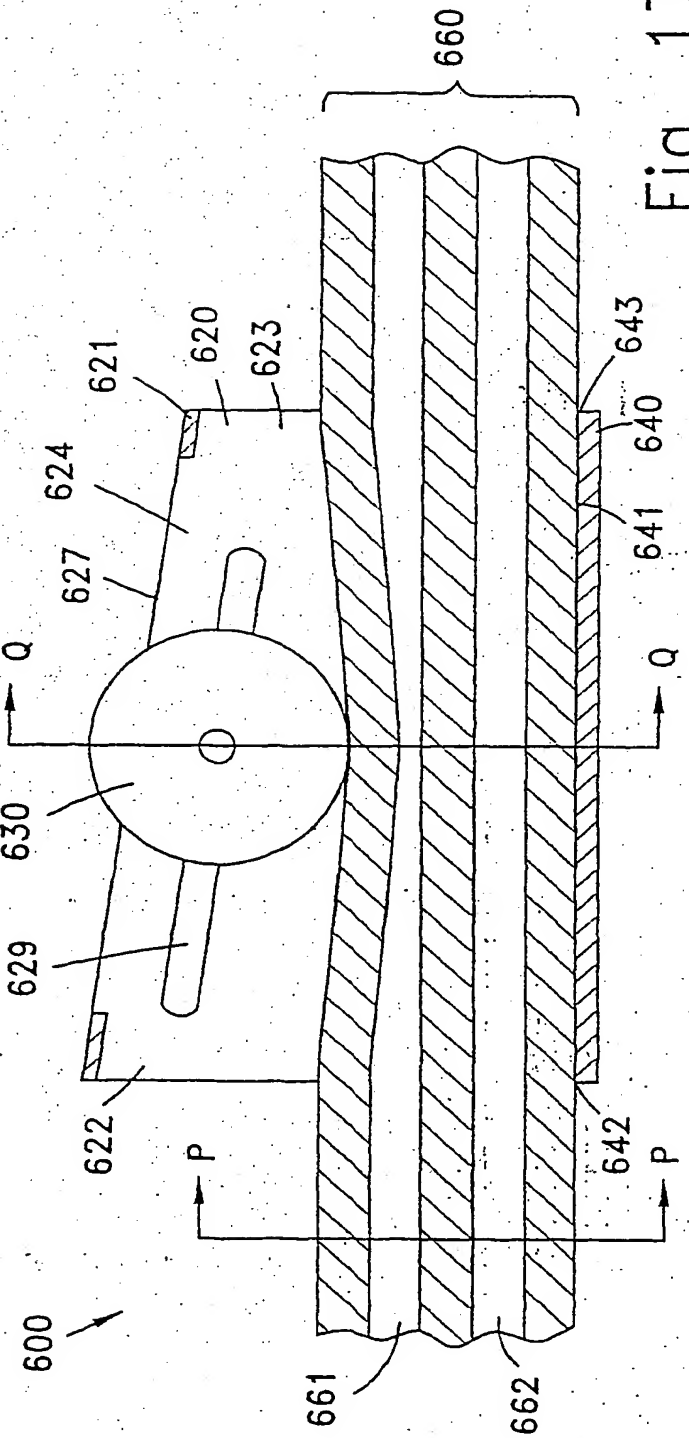

Fig. 17(a)

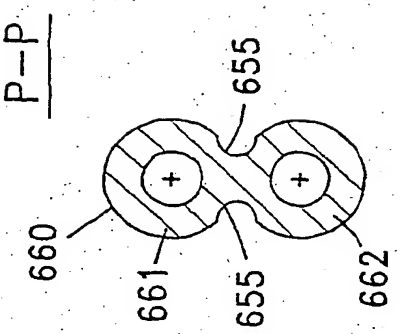

Fig. 17(c)

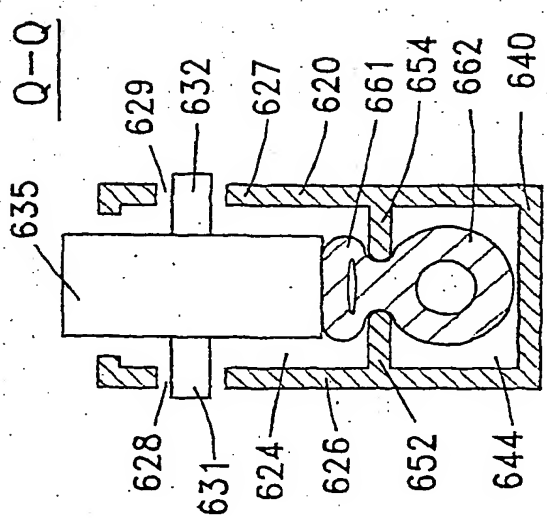

Fig. 17(b)

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(74) Agents: LUZZATTO, Kfir et al.; Luzzatto & Luzzatto, P.O. Box 5352, 84152 Beer-Sheva (IL).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

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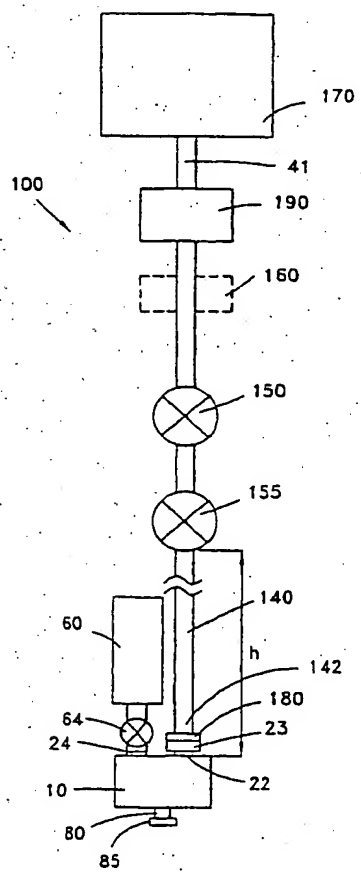
[Continued on next page]

(54) Title: PRIMING DEVICE FOR MEDICAL INFUSION SYSTEMS



(57) Abstract: A priming device for a medical infusion system is provided, for enabling a fluid delivery tubing operatively connected to a liquid source to be automatically primed with liquid from the source during operation of the device. The device has a fluid inlet in fluid communication with a bypass outlet via a chamber. The fluid inlet is adapted for operative connection with the delivery tubing, and the bypass outlet has suitable air venting means for air venting at least gas away from the chamber during operation of said device. A suitable valve is provided, the valve being adapted for enabling liquid communication between the chamber and a valve outlet to be selectively prevented or allowed during operation of said device, according to predetermined conditions. Suitable connectors at the valve outlet enable connection of the device to a patient interface end such as a cannula. Medical infusion systems, such as intravenous infusion administration sets, or dialysis or bypass blood systems, incorporating such a device are also provided.

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patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/IL 01/00497

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/36 A61M5/14 A61M5/168

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 308 333 A (SKAKOON JAMES G) 3 May 1994 (1994-05-03) cited in the application column 3, line 23 -column 4, line 16; figures 1-4	1-5,10, 12,14, 19-21, 30-34, 39,41, 75,82

X	US 4 177 808 A (MALBEC EDOUARD) 11 December 1979 (1979-12-11) column 1, line 55 -column 3, line 12; figures 1-3	1-4,7, 10,12, 19, 30-33, 39,82
A		15,42

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
6 December 2001	14/12/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Schönleben, J

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INTERNATIONAL SEARCH REPORT

International Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 042 038 A (BEACHAM ROBERT C) 3 July 1962 (1962-07-03) the whole document	1,2
A	US 3 677 248 A (MCPHEE CHARLES J) 18 July 1972 (1972-07-18) column 4, line 48 - line 67; figure 3	13,14, 40,41, 48-51, 69-71
A	US 5 935 105 A (LARKINS WILLIAM T ET AL) 10 August 1999 (1999-08-10) column 4, line 20 - line 30; figures 1,2	17,61,76
A	US 6 013 060 A (WOODARD ROBERT W) 11 January 2000 (2000-01-11) column 3, line 11 -column 4, line 29; figures 1,5	15,28, 36,37, 42,76

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IL 01/00497

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US 3042038	A	03-07-1962	NONE		
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